

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



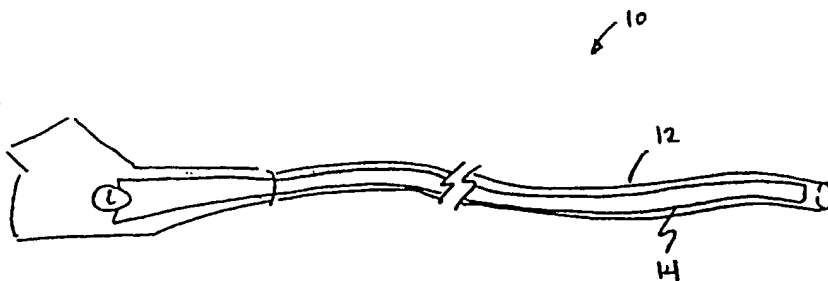
(43) International Publication Date
7 October 2004 (07.10.2004)

PCT

(10) International Publication Number
WO 2004/084702 A2

- (51) International Patent Classification⁷: **A61B** Redwood City, CA 94061 (US). ARNE, Lawrence, W. [US/US]; 24 Fulton Street, Redwood City, CA 94062 (US).
- (21) International Application Number: PCT/US2004/006939 (74) Agent: GLENN, Benjamin; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304 (US).
- (22) International Filing Date: 5 March 2004 (05.03.2004) (81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
10/384,252 7 March 2003 (07.03.2003) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 10/384,252 (CIP)
Filed on 7 March 2003 (07.03.2003)
- (71) Applicant (*for all designated States except US*): NEOGUIDE SYSTEMS, INC. [US/US]; 548 Division Street, Campbell, CA 95008 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): WHITIN, Katherine [US/US]; 31 Haciendas Drive, Woodside, CA 94062 (US). OHLINE, Robert, M. [US/US]; 330 Nimitz Avenue, Redwood City, CA 94061 (US). BELSON, Amir [IL/US]; Apt. C, 20070 Rodriguez Avenue, Cupertino, CA 95014 (US). ROTH, Alex [US/US]; 1354 Regent Street,
- (84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— *without international search report and to be republished upon receipt of that report*
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: METHOD AND APPARATUS FOR TRACKING INSERTION DEPTH



(57) Abstract: Methods and apparatus for tracking insertion depth of endoscopes are described herein. One method for determining endoscopic insertion depth within a body is to utilize a fully instrumented endoscope configured to determine its depth of insertion. Another method uses a datum device which interacts with the endoscope to determine how much of the endoscope has passed by a reference boundary. A fully instrumented endoscope can poll the status of the entire endoscope and then determine its position relative to anatomical boundaries, e.g., the anus. The polled information is obtained by sensors or transponders located along the length of the endoscope. When using an endoscope with a datum, the datum can read positional information by polling the status of sensors or transponders located along the body of the endoscope as the endoscope passes through the anus. The datum can be affixed to the patient or to another fixed reference point.

WO 2004/084702 A2

METHOD AND APPARATUS FOR TRACKING INSERTION DEPTH

FIELD OF THE INVENTION

[0001] The present invention relates generally to endoscopes and endoscopic medical procedures. More particularly, it relates to methods and apparatus for tracking the insertion and/or withdrawal of a flexible endoscope along a tortuous path, such as for colonoscopic examination and treatment.

BACKGROUND OF THE INVENTION

[0002] An endoscope is a medical instrument for visualizing the interior of a patient's body. Endoscopes can be used for a variety of different diagnostic and interventional procedures, including colonoscopy, bronchoscopy, thoracoscopy, laparoscopy and video endoscopy.

[0003] Colonoscopy is a medical procedure in which a flexible endoscope, or colonoscope, is inserted into a patient's colon for diagnostic examination and/or surgical treatment of the colon. A standard colonoscope is typically 135-185 cm in length and 12-19 mm in diameter, and includes a fiberoptic imaging bundle or a miniature camera located at the instrument's tip, illumination fibers, one or two instrument channels that may also be used for insufflation or irrigation, air and water channels, and vacuum channels. The colonoscope is usually inserted via the patient's anus and advanced through the colon, allowing direct visual examination of the colon, the ileocecal valve and portions of the terminal ileum. Insertion of the colonoscope is complicated by the fact that the colon represents a tortuous and convoluted path. Considerable manipulation of the colonoscope is often necessary to advance the colonoscope through the colon, making the procedure more difficult and time consuming and adding to the potential for complications, such as intestinal perforation. Steerable colonoscopes have been devised to facilitate selection of the correct path through the curves of the colon. However, as the colonoscope is inserted farther and farther into the colon, it becomes more difficult to advance the colonoscope along the selected path. At each turn, the wall of the colon must maintain the curve in the

colonoscope. The colonoscope rubs against the mucosal surface of the colon along the outside of each turn. Friction and slack in the colonoscope build up at each turn, making it more and more difficult to advance and withdraw the colonoscope. In addition, the force against the wall of the colon increases with the buildup of friction. In cases of extreme tortuosity, it may become impossible to advance the colonoscope all of the way through the colon.

[0004] Another problem which arises, for example, in colonoscope procedures, is the formation of loops in the long and narrow tube of the colonoscope. Such loops may arise when the scope encounters an obstacle, or gets stuck in a narrow passage. Instead of progressing, the scope forms loops within the patient. In an attempt to proceed in insertion of the colonoscope, excess force may be exerted, damaging delicate tissue in the patient's body. The physician may proceed with the attempted insertion of the endoscope without realizing there is a problem.

[0005] Through a visual imaging device the user can observe images transmitted from the distal end of the endoscope. From these images and from knowledge of the path the endoscope has followed, the user can ordinarily determine the position of the endoscope. However, it is difficult to determine the endoscope position within a patient's body with any great degree of accuracy. This becomes even more difficult when attempting to determine endoscopic positioning using, e.g., automatically controlled endoscopic devices, as described in U.S. Pat. No. 6,468,203; U.S. Pat. App. No. 09/969,927 filed October 2, 2001; U.S. Pat. App. No. 10/229,577 filed August 27, 2002; U.S. Pat. App. No. 10/087,100 filed March 1, 2002; and U.S. Pat. App. No. 10/139,289 filed May 2, 2002, each of which is incorporated herein by reference in its entirety.

[0006] Another method used to determine the configuration of the endoscope is x-ray imaging. Yet another method used is magnetic field positioning, which avoids the x-ray exposure to the patient and the operator. Such a method typically uses magnetic position determination via low frequency magnetic fields to determine the position of a miniature sensor embedded within

- 3 -

the endoscope tube. Based on the position of the sensor at sequential time periods, an image of the configuration of the endoscope tube is produced.

[0007] Another method involves the placement of a series of markings on the endoscope that can aid the physician in proper placement of the device in the patient's body during a procedure. These markings can include bands, dots, lettering, numbering, colors, or other types of indicia to indicate position or movement of the device within the body. Visually distinguishable marks are often located at regular predetermined intervals. Such a system of indicia can be made to be visible under fluoroscopy by the use of certain radiopaque metals, or compounds incorporated into or printed on the device.

[0008] However, each of these methods are limited in their flexibility and applicability when the position of the endoscope within a patient's body is desired with any accuracy. Furthermore, such conventional position determination methods in many cases may also fail to account for the real-time position of the endoscope during advancement and/or withdrawal into the patient.

BRIEF SUMMARY OF THE INVENTION

[0009] The information on the length of an endoscope or colonoscope inserted into a body organ within a patient may be used to aid in mapping the body organ, anatomical landmarks, anomalies, etc., and/or to maintain real-time knowledge along the entire length of the endoscope position within the body. This is particularly useful when used in conjunction with various endoscopes and/or colonoscopes having a distal steerable portion and an automatically controlled proximal portion which may be automatically controlled by, e.g., a controller. Examples of such devices are described in detail in the following granted patents and co-pending applications: U.S. Pat. No. 6,468,203; U.S. Pat. App. No. 09/969,927 filed October 2, 2001; U.S. Pat. App. No. 10/229,577 filed August 27, 2002; U.S. Pat. App. No. 10/087,100 filed March 1, 2002; and U.S. Pat. App. No. 10/139,289 filed May 2, 2002, each of which has been incorporated by reference above.

[0010] One method for determining endoscopic insertion depth and/or position is to utilize a fully instrumented endoscopic device which incorporates features or elements configured to determine the endoscope's depth of insertion without the need for a separate or external sensing device and to relay this information to the operator, surgeon, nurse, or technician involved in carrying out a procedure. Another method is to utilize a sensing device separate from and external to the endoscope that may or may not be connected to the endoscope and which interacts with the endoscope to determine which portion of the endoscope has passed through or by a reference boundary. The external sensing device may also be referred to herein interchangeably as a datum or datum device as it may function, in part, as a point of reference relative to a position of the endoscope and/or patient. This datum may be located externally of the endoscope and either internally or externally to the body of the patient; thus, the interaction between the endoscope and the datum may be through direct contact or through non-contact interactions.

[0011] An instrumented endoscope may accomplish measurement by polling the status of the entire scope (or at least a portion of the scope length), and then determining the endoscope position in relation to an anatomical boundary or landmark such as, e.g., the anus in the case of a colonoscope. The polled information may be obtained by a number of sensors located along the length of the device. Because the sensed information may be obtained from the entire endoscope length (or at least a portion of its length), the direction of endoscope insertion or withdrawal from the body may be omitted because the instantaneous status of the endoscope may be provided by the sensors.

[0012] Aside from endoscopes being instrumented to measure insertion depth, other endoscope variations may be used in conjunction with a separate and external device that may or may not be attached to the body and which is configured to measure and/or record endoscope insertion depth. This device may be referred to as an external sensing device or as a datum or datum device. These terms are used interchangeably herein as the external sensing device may function, in part, as a point of reference relative to a position of the endoscope

- 5 -

and/or patient. This datum may be located externally of the endoscope and either internally or externally of the body of the patient; thus, the interaction between the endoscope and the datum may be through direct contact or through non-contact interactions. Moreover, the datum may be configured to sense or read positional information by polling the status of sensors, which may be located along the body of the endoscope, as the endoscope passes into the body through, e.g., the anus. The datum may be positioned external to the patient and located, e.g., on the bed or platform that the patient is positioned upon, attached to a separate cart, or removably attached to the patient body, etc.

[0013] If the patient is positioned so that they are unable to move with any significant movement during a procedure, the datum may function as a fixed point of reference by securing it to another fixed point in the room. Alternatively, the datum may be attached directly to the patient in a fixed location relative to the point of entry of the endoscope into the patient's body. For instance, for colonoscopic procedures the datum may be positioned on the patient's body near the anus. The location where the datum is positioned is ideally a place that moves minimally relative to the anus because during such a procedure, the patient may shift position, twitch, flex, etc., and disturb the measurement of the endoscope. Therefore, the datum may be positioned in one of several places on the body.

[0014] One location may be along the natal cleft, i.e., the crease defined between the gluteal muscles typically extending from the anus towards the lower back. The natal cleft generally has little or no fat layers or musculature and does not move appreciably relative to the anus. Another location may be directly on the gluteal muscle adjacent to the anus.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Fig. 1A shows an example of an endoscope having an electrical circuit throughout the length of the instrument.

[0016] Fig. 1B shows an example of the device of Fig. 1A prior to being inserted into a patient.

[0017] Fig. 1C shows a device sensing its position as it is advanced through the anus of the patient.

[0018] Fig. 1D shows a cross-sectional view of one variation of the endoscope of Fig. 1A.

[0019] Figs. 2A and 2B show an endoscopic device having a series of individual sensors or switches for sensing its insertion depth or position.

[0020] Fig. 3A shows another example of an endoscope which may have a number of sensors positioned along the length at discrete locations.

[0021] Fig. 3B shows the device of Fig. 3A with individual sensor wires leading to each of the sensors along the length.

[0022] Fig. 4 shows another example in which pairs of sensor wires may be placed along the length of the endoscope terminating at discrete locations.

[0023] Figs. 5A to 5D show another example of an endoscope in which the endoscope position may be determined in part by the resistance measured between adjacent sensor rings.

[0024] Fig. 6 shows an example of an algorithm which may be utilized for determining and recording insertion depth of an endoscope.

[0025] Figs. 7A and 7B show an example of an endoscope which may utilize an external device for determining endoscope position.

[0026] Fig. 7C shows another example of an endoscope having a non-uniform diameter utilizing an external device for determining endoscope position.

[0027] Fig. 8 shows another example of an external device which may be used to determine endoscope position.

[0028] Fig. 9 shows another example of an external device which may be used to detect sensors positioned on the endoscope.

[0029] Fig. 10 shows one example of determining endoscope insertion and/or withdrawal using at least two sensors.

[0030] Figs. 11A and 11B show examples of plots indicating sensor readings from the two sensors of Fig. 10 which may be used to determine whether the endoscope is being advanced or withdrawn.

[0031] Figs. 12A to 12D show at least four situations, respectively, on how the direction of travel for the endoscope may be determined using the two sensors of Fig. 10.

[0032] Fig. 13 shows an example of an algorithm which may be utilized for determining the endoscope direction of travel.

[0033] Fig. 14 shows a simplified example for determining endoscope position with an external device.

[0034] Fig. 15 shows an example illustrating the positioning which may be utilized for an external device with an endoscope.

[0035] Fig. 16 shows a schematic variation utilizing a single magnetic device and multiple sensors.

[0036] Figs. 17A and 17B illustrate one example for sensing individual segments of an endoscopic device as it passes the sensor.

[0037] Fig. 18 shows another example for sensing individual segments of an endoscopic device having discrete permanent magnets or electromagnets positioned along the endoscope.

[0038] Figs. 19A and 19B illustrate another example for sensing individual segments of an endoscopic device using multiple permanent magnets or electromagnets.

[0039] Fig. 20 shows only the vertebrae of an endoscopic device, for clarity, with discrete permanent magnets or electromagnets positioned along the endoscope.

[0040] Figs. 21A and 21B show side and cross-sectional views, respectively, of another example for magnet positioning along the endoscope.

[0041] Figs. 22A and 22B show another example for applying ferrous material, other materials that may alter or affect a magnetic field, permanent magnets, or electromagnets along the endoscope.

[0042] Fig. 23 shows another example in which magnets or ferrous material, or other materials that may alter or affect a magnetic field, may be positioned along an elongate support or tool which may then be positioned within the working lumen of a conventional endoscope.

[0043] Figs. 24A to 24C show various examples for attaching ferrous materials or other materials that may alter or affect a magnetic field to individual vertebrae of an endoscope.

[0044] Figs. 25A and 25B show examples of alternative sensing mechanisms using, e.g., force measurement.

[0045] Figs. 26A and 26B show another example of alternative sensing mechanisms using, e.g., a rotatable wheel having discrete permanent magnets or electromagnets integrated within or upon the wheel.

[0046] Fig. 27 shows one example of a datum which may be positioned along or within the natal cleft.

[0047] Fig. 28 shows another example of a datum which may also be aligned along or within the natal cleft using a flexible and elongate member.

[0048] Figs. 29A and 29B show one possible configuration for the datum sensor.

[0049] Figs. 30 A and 30B show another example of datum positioning for securing the sensor to the patient.

[0050] Fig. 31 shows another example of a datum for use with a sensor within a disposable substrate.

[0051] Figs. 32A and 32B show another example of a datum which may be positioned on a single cheek adjacent to the anus.

[0052] Figs. 33A to 33C show another example of a datum which may also be positioned on a single cheek adjacent to the anus.

[0053] Fig. 34 shows yet another example of a datum which may also be positioned on a single cheek adjacent to the anus.

[0054] Fig. 35 shows yet another example of a datum having multiple sensors which may also be positioned on a single cheek adjacent to the anus.

[0055] Fig. 36 shows an example of an encased datum.

[0056] Fig. 37 shows an example of a datum which may be placed upon both cheeks while spanning the natal cleft.

[0057] Figs. 38A and 38B show an example of a datum which may be used to encircle the endoscope when in use.

[0058] Fig. 39 shows an example of a datum which may be incorporated into the fabric of an undergarment in the region surrounding the anus.

DETAILED DESCRIPTION OF THE INVENTION

[0059] A determination of the length of an endoscope or colonoscope inserted into a body organ within a patient, or generally into any enclosed space, is useful information which may be used to aid in mapping the body organ, anatomical landmarks, anomalies, etc., and/or to maintain real-time knowledge of the endoscope position within the body. The term endoscope and colonoscope may be used herein interchangeably but shall refer to the same type of device. This is particularly useful when used in conjunction with various endoscopes and/or colonoscopes having a distal steerable portion and an automatically controlled proximal portion which may be automatically controlled by, e.g., a controller. Examples of such devices are described in detail in the following granted patents and co-pending applications: U.S. Pat. No. 6,468,203; U.S. Pat. App. No. 09/969,927 filed October 2, 2001; U.S. Pat. App. No. 10/229,577 filed August 27, 2002; U.S. Pat. App. No. 10/087,100 filed March 1, 2002; and U.S. Pat. App. No. 10/139,289 filed May 2, 2002, each of which has been incorporated by reference above.

[0060] There are at least two different approaches which may be utilized in determining endoscopic insertion depth and/or position when an endoscope has been inserted within the body. One method is to utilize a fully instrumented endoscopic device which incorporates features or elements which are configured to determine the endoscope's depth of insertion and to relay this information to the operator, surgeon, nurse, or technician involved in carrying out a procedure.

[0061] Another method is to utilize a sensing device separate from and external to the endoscope and which interacts with the endoscope to determine which portion of the endoscope has passed through or by a reference boundary. The external sensing device may also be referred to herein interchangeably as a datum or datum device as it may function, in part, as a point of reference relative to a position of the endoscope and/or patient. This datum may be located

- 10 -

externally of the endoscope and either internally or externally to the body of the patient; thus, the interaction between the endoscope and the datum may be through direct contact or through non-contact interactions.

INSTRUMENTED ENDOSCOPES

[0062] One method of determination for endoscopic insertion depth and/or position is through an endoscopic device which may be configured to determine its depth of insertion. That is, an endoscopic device may be configured to indicate the portion of the endoscope that has been inserted into a body organ without the need for a separate or external sensing device. This type of determination may reflect an endoscope configured such that its depth measurement is independent of its progress during insertion or withdrawal into the body organ and instead reflects its depth instantaneously without regards to its insertion history.

[0063] Such an endoscopic device may accomplish this, in part, by polling the status of the entire scope (or at least a portion of the scope length), and then determining the endoscope position in relation to an anatomical boundary or landmark such as, e.g., the anus in the case of a colonoscope. The polled information may be obtained by a number of sensors located along the length of the device, as described in further detail below. Because the sensed information may be obtained from the entire endoscope length (or at least a portion of its length), the direction of endoscope insertion or withdrawal from the body may be omitted because the instantaneous status of the endoscope may be provided by the sensors. Directional information or history of the endoscope position during an exploratory or diagnostic procedure may optionally be recorded and/or stored by reviewing the endoscope time history of insertion depth.

[0064] One variation is seen in Fig. 1A which shows endoscope assembly 10. Endoscope 12 may be configured to have at least a single circuit 14 wired through the length of the shaft of endoscope 12. Circuit 14 may also be wired through only a portion of the shaft length or through a majority of the shaft length depending upon the desired proportion of the shaft that the operator, surgeon, or technician desires to act as a sensor. The single circuit 14 may thus configure the

endoscope 12 to function as a single continuous sensor. Depending upon the type of sensors implemented, as described in further detail below, changes in an output variable received by the sensors may be measured and recorded. The degree of change in the output variable may then be correlated to the length of the endoscope 12 inserted into the body. The change in the output variable may also be based upon varying environmental factors experienced by the endoscope 12. For instance, one example of an environmental factor which may instigate changes in the output variable sensed by the circuit 14 may include pressure sensed from the surrounding tissue, e.g., from the anus, where endoscope 12 is initially inserted into the body. Another factor may include changes in electrical conductivity, e.g., from the tissue, when the endoscope 12 is inserted into the body.

[0065] Endoscope 12 may alternatively be configured to detect and correlate the length of the endoscope 12 remaining outside the body rather than inside the body to indirectly calculate the insertion depth. Moreover, the endoscope 12 may additionally detect and correlate both the length of the endoscope 12 remaining outside the body as well as the length of endoscope 12 inserted within the body. Alternatively, endoscope 12 may sense the location of the orifice or anus 20 along the length of the device and then calculate either the length remaining outside the body or the insertion length relative to the position of anus 20.

[0066] Another example of changing environmental factors leading to a change in an output variable is shown in Figs. 1B and 1C, which show an example of endoscope assembly 10 configured as a capacitive sensing endoscopic device. As seen in Fig. 1B, patient 18 may be positioned upon table and/or grounding pad 16 which may be connected to electrical ground 22. Fig. 1C shows endoscope 12 inserted within anus 20 of patient 18. Prior to or while endoscope 12 is inserted in patient 18, a constant input current may be provided to endoscope 12 and the voltage may be measured in accordance. Endoscope 12 may thus act as a plate within a capacitor while grounding pad 16 placed under patient 18 may function as a second opposing plate to endoscope 12, as represented in the schematic 24.

- 12 -

The resulting capacitance between endoscope 12 and grounding pad 16 may be calculated based upon the value of the current, i , over a time period, t , and/or upon the measured difference in phase shift between the input frequency and the resulting frequency. As endoscope 12 is inserted or withdrawn from anus 20, the calculated capacitance will vary according to differences in the dielectric constants between the tissue of patient 18 and that of air. This capacitance change may be constantly monitored and mapped against the length of endoscope 12 to indicate the length of insertion within patient 18.

[0067] Another variation on endoscopic sensing may utilize resistivity rather than capacitance. For instance, continuous circuit 14 may be configured into a single printed circuit with an overlay of conductive printed carbon. Fig. 1D shows one variation on a cross-section of endoscope 12 which may be configured as such. As seen, conductive printed carbon layer 25 may be positioned circumferentially within printed flex circuit 26 while surrounding endoscope interior 28. The endoscope 12 may be optionally covered by an outer jacket or sheath 27 to cover the endoscope and its electronics. In use, when the endoscope 12 is inserted into the patient 18 through, e.g., the anus 20, pressure from the surrounding tissue at the point of insertion into the body may force contact between carbon layer 25 and flex circuit 26 within endoscope 12 and thereby close the circuit 14 at the point of insertion. As endoscope 12 is inserted and withdrawn from anus 20, the contact point between carbon layer 25 and flex circuit 26 will vary according to where the pressure is applied at the point of insertion and the resistance of the circuit 14 at any one time may be measured and mapped against the length of endoscope 12 to indicate the length of insertion within anus 20.

[0068] Another variation is shown in Figs. 2A and 2B, which show an endoscopic device having a series of individual sensors or switches for sensing its insertion depth or position. Endoscope 30 is shown as having a continuous circuit with a plurality of open, individual switches or conductive sections 32 positioned along the length of the device 30. Switches, S_1 to S_N , may be positioned at regular intervals along endoscope 12. The spacing between the switches may vary and

may depend upon the desired degree of accuracy in endoscope position determination. Switches may be positioned closely to one another to provide for a more accurate reading, while switches spaced farther apart from one another may provide for a less accurate determination. Moreover, the switches may be positioned at uniform distances from one another, or alternatively they may be spaced apart at irregular intervals, depending upon the desired results. The switches may also take a variety of electrically conductive forms, e.g., membrane switches, force sensitive resistors (FSR), etc.

[0069] Another variation on the type of switch which may be used is light-detecting transducers. The switches S_1 to S_N , may be configured as one of a variety of different types of photo-sensitive switches, e.g., photoemissive detectors, photoconductive cells, photovoltaic cells, photodiodes, phototransistors, etc. The switches S_1 to S_N , may be located at predetermined positions along the length of the endoscope 30. As the endoscope 30 is inserted into the patient 18, the change in ambient light from outside the patient 18 to inside the patient 18 may result in a voltage change in the switches inserted within the body 18. This transition may thereby indicate the insertion depth of the endoscope 30 within the body 18 or the length of the endoscope 30 still located outside the body 18. The types of photo-sensitive switches aforementioned may have a current running through them during a procedure, with the exception of photovoltaic switches, which may be powered entirely by the ambient light outside the body 18.

[0070] Fig. 2B shows a schematic representation 34 of the device of Fig. 2A. As shown, switches, S_1 to S_N , may be configured such that they are in parallel to one another. Insertion or withdrawal of the endoscope 12 within patient 18 may activate or close a switch through, e.g., interaction with electrically conductive tissue, pressure from the anus closing the switch, changes in moisture or pH, temperature changes, light intensity changes, etc. The closing of a particular switch will vary according to how deep the endoscope 12 is inserted within the anus 20. When a particular switch is electrically activated, a corresponding resistance value, ranging from R_1 to R_N , may be measured and then mapped against the endoscope 12 to indicate the length of insertion.

- 14 -

[0071] Another variation is shown in Figs. 3A and 3B which show an endoscope 40 having a number of sensors positioned along the length of the endoscope 40 at discrete locations. In this variation, a number of sensor wires may be placed along the length of the endoscope 12 such that each wire terminates at subsequent locations along the endoscope 12, as shown in Fig. 3B. Although only three wires are shown, this is merely intended to be illustrative and any number of fewer or additional wires may be utilized depending upon the desired length of the endoscope 12 to be instrumented. The placement of the distal ends of sensor wires 46', 48', 50' may coincide with the number of vertebrae or links of the endoscope 12 structure. The sensor wires 46', 48', 50' may be simply routed through within the endoscope 12 length or they may be placed along the exterior of the device. The distal ends of the wires may be exposed to allow for communication with the tissue or they may alternatively be each connected to corresponding conductors 42 which divide the endoscope 12 up into a number of segments 44. These optional conductors 42 may be formed in the shape of rings to allow for circumferential contact with the tissue. Each sensor wire 46', 48', 50' may thus be in electrical communication with a corresponding conductor 46, 48, 50, respectively, and so on, depending upon the number of wires and corresponding conductors utilized. The individual sensors may also be networked together on a single bus and more complex networking and placement of sensors may also be implemented to yield additional information, e.g., rotational position of the endoscope 12. The proximal ends of the sensor wires 46', 48', 50' may each be connected to a corresponding processor 52, 54, 56, respectively, such that the length of the endoscope 12 inserted within the anus 20 may be determined by polling the status of each individual sensor wire 46', 48', 50'.

[0072] Fig. 4 shows another endoscopic assembly variation 60 in which corresponding pairs of wire sensors may be positioned along an endoscope 62 body. A first pair 64 of wire sensors may extend along the endoscope 62 and terminate at a first distal location; a second pair 66 of wire sensors may also extend along the endoscope 62 and terminate at a second distal location which is

- 15 -

proximal of the first distal location; and a third pair 68 of wire sensors may also extend along the endoscope 62 and terminate at a third distal location which is proximal of the second distal location, and so on. Any number of wire pairs may be used and the distances between each of the first, second, third, etc., distal locations may be uniform or irregular, depending upon the desired measurement results. This variation 60 may operate in the same manner as above by measuring which pair of wire sensors is disrupted when inserted or withdrawn from a patient.

[0073] Yet another example is shown in Figs. 5A to 5D which shows endoscope assembly 70 which may comprise an endoscope 72 having at least one or more, preferably at least two or more, conductive sensors 74 positioned along the length of endoscope 72. Sensors 74 may be in the shape of rings and may be further configured to measure resistance between each adjacent ring. Fig. 5B is a detailed view of a portion of endoscope 72 which shows first sensor 76 and adjacent second sensor 78. Each sensor 76, 78 may be connected to a separate sensor wire 76', 78' such that the electrical resistance, e.g., R_1 , between adjacent sensors, e.g., sensors 76, 78, may be measured when contacting a region of tissue. Fig. 5C shows sensors 76, 78 contacting tissue 79. As the endoscope 72 is advanced or withdrawn from the tissue, resistance values between adjacent sensors may be measured to determine the position of the endoscope 72 within the patient 18. As seen in Fig. 5D, resistance values may be subsequently measured between each adjacent sensor, shown as sensors 1, 2, 3, etc., as the device is advanced into patient 18. This may be accomplished, in part, by correlating measured resistance values between sensors where $R \approx \infty$ when sensors are measured outside of the body, and $R \ll \infty$ when sensors are measured inside the body when surrounded by tissue.

[0074] As mentioned above, other output variables aside from pressure or force, capacitance, and resistance measurements may also be employed to determine endoscopic insertion depth. For instance, moisture or pH sensors may be utilized since moisture or pH values change dramatically with insertion into the body. Temperature or heat flux sensing may also be utilized by placing temperature sensors, e.g., thermistors, thermocouples, etc., at varying locations

along the endoscope body. Temperature sensing may take advantage of the temperature differences between air and the body. Another alternative may include heating or cooling the interior of the endoscope at ranges above or below body temperature. Thus, the resultant heat flux into or out of the endoscope, depending upon the interior endoscope temperature, may be monitored to determine which portion of the endoscope are in contact with the body tissue. Another alternative may include light sensing by positioning light sensors at locations along the endoscope body. Thus, light intensity differences may be determined between outside and inside the body to map endoscope insertion depth. Alternatively, sound waves or other pressure waves, ultrasound, inductive proximity sensors, etc., may also be utilized.

[0075] In utilizing sensors positioned upon the endoscope body, an algorithm may be utilized for determining and recording the insertion depth of the endoscope within a patient, as shown in Fig. 6. This variation on an algorithm operates on the general principle that each of the sensors are triggered sequentially as the endoscope is inserted or withdrawn from the patient. A register may be used to record and keep track of the latest insertion depth, i.e., the most recent and valid triggered sensor. The endoscope and algorithm may be configured such that sensor readings that are considered valid are those readings which are triggered by the same sensor or adjacent sensors such that insertion, withdrawal, or no motion may be indicated. Other sensor triggers can be ignored or rejected while valid sensor triggers may cause the register to update.

[0076] Such an algorithm may be implemented with any of the devices described above to eliminate false measurements and to maintain accurate insertion depth measurements. Step 80 indicates the start of the algorithm as the endoscope waits for a sensor to be triggered 82. If a sensor has not been triggered 84, the algorithm would indicate a "No" and the device would continue to wait for a trigger signal. Upon an indication that a sensor has been triggered 84, a comparison of the triggered signal takes place to compare whether the sensed signal is from an adjacent sensor 85 by comparing the triggered sensor information to stored register information in sensor register 88. If the triggered

- 17 -

signal is not from an adjacent sensor, the signal is rejected as a false signal 87 and the endoscope goes back to waiting for a sensor to be triggered 82. However, if the triggered signal is from an adjacent sensor when compared to the value stored in register 88, register 88 is updated 86 with the new sensor information and the endoscope then continues to wait for another sensor to be triggered 82.

ENDOSCOPES USING EXTERNAL SENSING DEVICES

[0077] Aside from endoscopes being instrumented to measure insertion depth, other endoscopes may be used in conjunction with a separate device configured to measure and/or record endoscope insertion depth. This separate device may be referred to as an external sensing device or as a datum or datum device. These terms are used interchangeably herein as the external sensing device may function, in part, as a point of reference relative to a position of the endoscope and/or patient. This datum may be located externally of the endoscope and either internally or externally to the body of the patient; thus, the interaction between the endoscope and the datum may be through direct contact or through non-contact interactions. Moreover, the datum may be configured to sense or read positional information by polling the status of sensors or transponders, which may be located along the body of the endoscope, as the endoscope passes into the body through, e.g., the anus. Alternatively, the datum may be configured to detect sensors or transponders only within a limited region or area. The datum may be positioned external to the patient and located, e.g., on the bed or platform that the patient is positioned upon, attached to a separate cart, or removably attached either internally or externally to the patient body, etc.

[0078] Figs. 7A and 7B show one variation in using an endoscope assembly 90 in conjunction with external sensing device or datum 96. Datum 96 may be positioned externally of patient 18 adjacent to an opening into a body cavity, e.g., anus 20 for colonoscopic procedures. Datum 96 may accordingly have a sensor or reader 98 located next to opening 100, which may be used as a guide for passage of endoscope 92 therethrough into anus 20. Endoscope 92 may be configured to have a number of tags 94, e.g., sensors, transponders, etc.,

located along the body of endoscope 92. These tags 94 may be positioned at regular intervals along endoscope 92. The spacing between the tags 94 may vary and may also depend upon the desired degree of accuracy in endoscope position determination. Tags 94 may be positioned closely to one another to provide for a more accurate reading, while tags 94 spaced farther apart from one another may provide for a less accurate determination. Moreover, tags 94 may be positioned at uniform distances from one another, or alternatively they may be spaced apart at irregular intervals, depending upon the desired results. Moreover, tags 94 may be positioned along the entire length of endoscope 92 or only along a portion of it, depending upon the desired results. As shown in Fig. 7B, as endoscope 92 is passed through datum 96 via opening 100 and into anus 20, reader 98 located within datum 96 may sense each of the tags 94 as they pass through opening 100. Accordingly, the direction and insertion depth of endoscope 92 may be recorded and/or maintained for real-time positional information of the endoscope 92.

[0079] Any number of technologies may be utilized with tags 94. For instance, one variation may have tags 94 configured as RF identification tags or antennas. Reader 98 may accordingly be configured as a RF receiving device. Each tag 94 may be encoded with, e.g., position information such as the distance of a particular tag 94 from the distal end of endoscope 92. The reader 98 may be configured to thus read in only certain regions or zones, e.g., reader 98 may read only those RF tags passing through opening 100 or only those tags adjacent to anus 20. Alternatively, the RF tags may be configured to transmit the status of, e.g., pressure switches as described above, to datum 96 to determine the length of insertion.

[0080] Another variation on tags 94 may be to configure the tags for ultrasonic sensing. For example, each tag 94 may be configured as piezoelectric transducers or speakers positioned along the endoscope 92. The reader 98 may thus be configured as an ultrasonic receiver for receiving positional information from tuned transducers or tags 94 each of which relay its positional information. Alternatively, optical sensors may be used as tags 94. In this variation, each tag 94 may be configured as a passive encoded marker located on an outer surface of

endoscope 92. These markers may be in the form of a conventional bar code, custom bar code, color patterns, etc., and each may be further configured to indicate directional motion, i.e., insertion or withdrawal. Furthermore, each tag 94 may be configured as active encoded markers, e.g., LEDs which may be blinking in coded patterns. Reader 98 may thus be configured as an optical sensor.

[0081] Another alternative may be to configure tags 94 and reader 98 for infrared (IR) sensing in which case IR emitters may be positioned along the length of endoscope 92 such that each IR emitter or tag 94 is configured to emit light at a specific frequency according to its position along the endoscope 92. Reader 98 may thus be configured as an IR receiver for receiving the different frequencies of light and mapping the specific frequency detected against the length of endoscope 92. Yet another alternative may be to have tags 94 configured magnetically such that a magnetic reader in datum 96 can read the position of the device, as described in further detail below.

[0082] Yet another alternative may be to configure the datum and endoscope assembly as a linear cable transducer assembly. In this variation, reader 98 may be configured as a transducer having a cable, wire, or some other flexible member extending from reader 98 and attached to the distal end of endoscope 92. While the datum 96 remains external to the patient and further remains in a fixed position relative to the patient, the endoscope 92 may be advanced within the patient while pulling the cable or wire from reader 98. The proximal end of the cable or wire may be attached to a spool of cable or wire in electrical communication with a multi-turn potentiometer. To retract the cable or wire when the endoscope 92 is withdrawn, the spool may be biased to urge the retraction of the cable or wire back onto the spool. Thus, the change of wire length may be correlated to an output of the reader 98 or of the potentiometer to a length of the extended cable and thus the length of the endoscope 92 inserted within the patient.

[0083] Yet another alternative may be to mount rollers connected to, e.g., multi-turn potentiometers, encoders, etc., on datum 96. These rollers may be

configured to be in direct contact with the endoscope 92 such that the rollers rotate in a first direction when endoscope 92 is advanced and the rollers rotate in the opposite direction when endoscope 92 is withdrawn. The turning and number of revolutions turned by the rollers may be correlated into a length of the insertion depth of endoscope 92.

[0084] Yet another alternative may be to use the endoscopes, or any of the endoscopes described herein, in conjunction with conventional imaging technologies which are able to produce images within the body of a patient. For instance, any one of the imaging technologies such as x-ray, fluoroscopy, computed tomography (CT), magnetic resonance imaging (MRI), magnetic field location systems, etc., may be used in conjunction with the endoscopes described herein for determining the insertion depth.

[0085] In yet another alternative, the datum may be used to sense the positional information from the endoscope through the use of one or several pressure sensors located on the datum, e.g., datum 96. The pressure sensor may be positioned upon datum 96 such that it may press up against the endoscope 92 as it is advanced or withdrawn. This pressure sensor may be configured, e.g., as a switch, or it alternatively be configured to sense certain features on the endoscope 92, e.g., patterned textures, depressions, detents, etc., which are located at predetermined lengths or length intervals to indicate to the pressure switch the insertion depth of endoscope 92.

[0086] Yet another alternative is to sense changes in the diameter of the endoscope body inserted into the patient, as seen in Fig. 7C. The insertion length of the endoscope may have multiple sections each having a unique diameter, e.g., a distal most section 102 may have the smallest diameter and each successive proximal section 104, 106 may have incrementally larger diameters.

Alternatively, successive sections may have alternating diameter sizes where a first section may have a first diameter, a second section may have a second larger diameter, and the third section may have a diameter equal to the first diameter or larger than the second diameter, and so on. The differences in endoscopic diameter may be used to detect the endoscopic insertion depth by using a datum

108 which may be configured to maintain contact with the endoscope and move according to the diameter changes of the endoscope, as shown by the arrows. This diameter referencing device and method may be used independently or in conjunction with any of the other methods described herein as a check to ensure that the position of the endoscope concurs with the results using other methods of sensing.

[0087] Fig. 8 shows another example in endoscope assembly 110 in which endoscope 112 may have a number of sensors or tags 114 located along the body of the endoscope 112. As endoscope 112 is advanced or withdrawn from anus 20, datum 116, which may be mounted externally of the patient and at a distance from endoscope 112, may have a receiver or reader 118 configured in any of the variations described above. For instance, receiver or reader 118 may be adapted to function as a RF receiver, ultrasonic receiver, optical sensor, or as any of the other variations described above, to read only those tags 114 adjacent to anus 20 and to map their position on the endoscope 112 and thus, the length of insertion.

[0088] If reader 118 were configured as an optical sensor, it may further utilize a light source, e.g., LED, laser, carbon, etc., within datum 116. This light source may be utilized along with a CCD or CMOS imaging system connected to a digital signal processor (DSP) within reader 118. The light may be used to illuminate markings located at predetermined intervals along endoscope 112. Alternatively, the markings may be omitted entirely and the CCD or CMOS imaging system may be used to simply detect irregularities normally present along the surface of an endoscope. While the endoscope is moved past the light source and reader 118, the movement of the endoscope may be detected and correlated accordingly to indicate insertion depth.

[0089] Fig. 9 shows another variation with endoscope assembly 120 in which endoscope 122 may have a number of sensors 124 located along the length of endoscope 122. These sensors 124 may be configured as Hall-effect type sensors, as will be described in greater detail below. The datum 126 may be configured as a ring magnet defining an endoscope guide 128 therethrough such that the magnetic field is perpendicularly defined relative to the sensors 124.

Thus, sensors 124 may interact with magnet 126 as they each pass through guide 128. As a Hall sensor 124 passes through datum 126, the sensor 124 may experience a voltage difference indicating the passage of a certain sensor through datum 126. These types of sensors will be described in greater detail below.

[0090] In order to determine the direction of the endoscope when it is either advanced or withdrawn from the patient, directional information may be obtained using any of the examples described above. Another example is to utilize at least two or more sensors positioned at a predetermined distance from one another. Fig. 10 shows one variation illustrating sensor detection assembly 130 with first sensor 132 and second sensor 134. First and second sensors 132, 134 may be positioned at a predetermined distance, d , from one another. As endoscope 136 is advanced or withdrawn past sensor assembly 130, the direction of travel 138 of endoscope 136 may be determined by examining and comparing the signals received from each sensor 132, 134. By determining which sensor has a rising edge or input signal first received relative to the other sensor, the direction of travel 138 may be determined. As shown in Fig. 11A, plot 140 generally illustrates signals received from first sensor 132. From position $x = 1$ to position $x = 2$, a rise in the signal is measured thus sensing a peak in advance of the signal measured from position $x = 1$ to position $x = 2$ in plot 142, which is the signal received from second sensor 134, as seen in Fig. 11B. Thus, a first direction of travel, e.g., insertion, may be indicated by the relative comparisons between signals in plots 140 and 142. If endoscope 136 were traveling in the opposite direction, e.g., withdrawal, second sensor 134 would sense a peak in advance of first sensor 132.

[0091] A more detailed description for determining the endoscope's direction of travel follows below. Figs. 12A to 12D illustrate various cases for determining endoscopic direction of travel using first sensor 150 and second sensor 152. First and second sensors 150, 152 are preferably at a predetermined distance from one another while an endoscope is passed adjacent to the sensors. For the purposes of this illustration, a direction to the right shall indicate a first direction of travel for an endoscope device, e.g., insertion into a body, while a

direction to the left shall indicate a second direction of travel opposite to the first direction, e.g., withdrawal from the body.

[0092] Fig. 12A shows a situation in which first sensor 150 measures a voltage less than the voltage measured by second sensor 152, as indicated by plot 154. If first and second sensors 150, 152 both measure a decrease in voltage, this may indicate a motion of the endoscope to the right while an increase voltage in both first and second sensors 150, 152 may indicate a motion of the endoscope to the left. Fig. 12B shows another situation in which first sensor 150 measures a voltage greater than the voltage measured by second sensor 152, as indicated by plot 156. If first and second sensors 150, 152 both measure an increase in voltage, this may indicate a motion of the endoscope to the right. However, if both first and second sensors 150, 152 measure a decrease in voltage, this may indicate a motion of the endoscope to the left.

[0093] Fig. 12C shows another situation where first sensor 150 measures a voltage equal to a voltage measured by second sensor 152, as shown by plot 158. In this case, if first sensor 150 measures an increase in voltage prior to second sensor 152 also measuring an increase in voltage, this may be an indication of the endoscope moving to the right. On the other hand, if second sensor 152 measures an increase prior to first sensor 150 measuring an increase in voltage, this may indicate movement of the endoscope to the left. Fig. 12D shows a final situation in plot 160 where first sensor 150 again measures a voltage equal to a voltage measured by second sensor 152. In this case, the opposite to that shown in Fig. 12C occurs. For instance, if the voltage measured by first sensor 150 decreases prior to the voltage measured by second sensor 152, this indicates a movement of the endoscope to the right. However, if second sensor 152 measures a voltage which decreases prior to a decrease in voltage measured by first sensor 150, this may indicate a movement of the endoscope to the left.

[0094] Fig. 13 shows one variation of an algorithm which may be implemented as one method for determining whether an endoscope is being advanced or withdrawn from the body. Fig. 13 illustrates how the various determinations described above may be combined into one variation for an

algorithm. As seen, the algorithm begins with step 170. In step 172 an initial step of determining whether first sensor 150 measures a voltage greater than second sensor 152 is performed. If first sensor 150 does measure a voltage greater than second sensor 152, then a second determination may be performed in step 174 where a determination may be made as to whether the voltages measured by both sensors 150, 152 are increasing or not. If both voltages are increasing, step 178 may indicate that the endoscope is being inserted. At this point, the position of the endoscope and its fractional position, i.e., the distance traveled by the endoscope since its last measurement, may be determined and the algorithm may then return to step 172 to await the next measurement.

[0095] If, however, first sensor 150 does not measure a voltage greater than second sensor 152 in step 172, another determination may be performed in step 176 to determine whether the voltages measured by sensors 150, 152 are equal. If the voltages are not equivalent, the algorithm proceeds to step 180 where yet another determination may be performed in step 180 to determine if both voltages are increasing. If they are not, then step 178 is performed, as described above. If both voltages are increasing, then step 184 may indicate that the endoscope is being withdrawn. At this point, the position of the endoscope and its fractional position, i.e., the distance traveled by the endoscope since its last measurement, may again be determined and the algorithm may then return to step 172 to await the next measurement.

[0096] In step 176, if the voltages measured by first sensor 150 and second sensor 152 are equivalent, then the algorithm may await to determine whether a peak voltage is detected in step 182. If a peak voltage is detected, step 186 increments the insertion count. However, if a peak is not detected, then step 188 decrements the insertion count. Regardless of whether the insertion count is incremented or decremented, the algorithm may return to step 172 to await the next measurement.

ENDOSCOPES USING MAGNETIC SENSING DEVICES

[0097] One particular variation on measuring endoscopic insertion depth may utilize magnetic sensing, in particular, taking advantage of the Hall effect. Generally, the Hall effect is the appearance of a transverse voltage difference in a sensor, e.g., a conductor, carrying a current perpendicular to a magnetic field. This voltage difference is directly proportional to the flux density through the sensing element. A permanent magnet, electromagnet, or other magnetic field source may be incorporated into a Hall effect sensor to provide the magnetic field. If a passing object, such as another permanent magnet, ferrous material, or other magnetic field-altering material, alters the magnetic field, the change in the Hall-effect voltage may be measured by the transducer.

[0098] Fig. 14 illustrates generally Hall effect sensor assembly 190 which shows conductor or sensor 192 maintained at a distance, d , as it is passed over magnets 194, 196, 198 at distances x_1 , x_2 , x_3 , respectively. Each magnet may be positioned such that the polarity of adjacent magnets is opposite to one another or such that the polarity of adjacent magnets is the same. As sensor 192 is passed, voltage differences may be measured to indicate which magnet sensor 192 is adjacent to.

[0099] Fig. 15 shows one variation illustrating the general application for implementing Hall effect sensors for endoscopic position measurement. As shown, sensor assembly 200 illustrates one variation having magnet 202 with first sensor 204 and second sensor 206 adjacent to magnet 202. Magnet 202 may be a permanent magnet or it may also be an electromagnet. First and second sensors 204, 206 are connected to a power supply (not shown) and are positioned from one another at a predetermined distance. Both sensors 204, 206 may also be located at a predetermined distance from magnet 202. A general representation of endoscope 208 is shown to reveal the individual links or vertebrae 210 that may comprise part of the structure of the endoscope, as described in further detail in any of the references incorporated above. Each vertebrae 210 is shown as being schematically connected to adjacent vertebrae via joints 212 which may allow for endoscope articulation through tortuous paths. Endoscope 208 may be passed by sensor assembly 200 at a predetermined distance as it is inserted or withdrawn

- 26 -

from an opening in a patient. Each or a selected number of vertebrae 210 may be made of a ferrous material or other material that may alter or affect a magnetic field or have ferrous materials incorporated in the vertebrae 210. Thus, as endoscope 208 passes first and second sensors 204, 206, the ferrous vertebrae 210 may pass through and disrupt a magnetic field generated by magnet 202 and cause a corresponding voltage measurement to be sensed by sensors 204, 206. Direction of travel for endoscope 208, i.e., insertion or withdrawal, as well as depth of endoscope insertion may be determined by applying any of the methods described above.

[0100] Another variation is shown in Fig. 16 which illustrates a schematic representation 220 of Hall effect sensing in which the sensors may be located on the endoscope 226 itself. Magnet 222 may be positioned adjacent to, e.g., the anus of a patient, such that endoscope 226 passes adjacent to magnet 222 when inserted or withdrawn from the patient. Endoscope 226 may have a number of discrete Hall switches 228 positioned along the body of endoscope 226. As endoscope 226 passes magnet 222, the magnetic field lines 224 may disrupt a switch 228 passing adjacently. Hall switches 228 may be bipolar, unipolar, latched, analog, etc. and may be used to determine the total resistance R_{1-2} in order to determine insertion length of the endoscope 226.

[0101] Figs. 17A and 17B show another variation for Hall sensor positioning. Fig. 17A shows a sensor assembly 230 adjacent to an individual vertebrae 232 of an endoscope. A single vertebrae 232 is shown only for the sake of clarity. As seen, when vertebrae 232 is directly adjacent to magnet 234, magnetic flux lines 238 are disrupted and are forced to pass through sensor 236. Flux lines 238 passing through sensor 236 may cause a disruption in the current flowing therethrough and may thus indicate the passage of the endoscope. Fig. 17B shows the assembly of Fig. 17A when endoscope 230 has been advanced or withdrawn fractionally such that magnet 234 is positioned inbetween adjacent vertebrae 232 and 232'. When a vertebra is not immediately adjacent to magnet 234, flux lines 238' may return to their normal undisturbed state such that sensor 236 is also undisturbed by magnetic flux. The resumption of current within

- 27 -

sensor 236 may indicate that endoscope 230 has been moved relative to sensor assembly 230.

[0102] Fig. 18 shows another variation in assembly 240 where a discrete magnet 248 may be positioned on individual vertebrae 242 to produce a more pronounced effect in sensor measurement. Magnets 248 may be positioned along the longitudinal axis of the endoscope for creating a uniform magnetic field radially about the endoscope. Discrete magnets 248 may be permanent magnets or they may alternatively be electromagnets. In either case, they may be placed on as many or as few vertebrae or at various selected positions along the endoscope body depending upon the desired measurement results. As shown, when vertebrae 242 having discrete magnet 248 mounted thereon is brought into the vicinity of magnet 244, the interaction between the magnets produces an enhanced flux interaction 250 such that Hall sensor 246 is able to sense a more pronounced measurement. The polarity of each individual magnet 248 located along the endoscope body may be varied from location to location but the polarity of adjacent magnets on the endoscope body are preferably opposite to one another.

[0103] Alternatively, a number of magnets each having a unique magnetic signature may be placed at predetermined positions along the length of the endoscope. Each magnet 248 may be mapped to its location along the endoscope so when a magnet having a specific magnetic signature is detected, the insertion depth of the endoscope may be correlated. The magnets 248 may have unique magnetic signatures, e.g., measurable variations in magnetic field strength, alternating magnetic fields (if electromagnets are utilized), reversed polarity, etc.

[0104] Figs. 19A and 19B show yet another variation in assembly 260 in which more than one magnet may be used in alternative configurations. A first magnet 262 may be positioned at an angle relative to a second magnet 264 such that the combined flux lines 268 interact in accordance with each magnet. Thus, the polarity of each magnet 262, 264 may be opposite to one another as shown in the figures. Sensor 266 may be positioned such that the undisturbed field lines 268 pass through sensor 266. As vertebrae 270 is passed adjacent to sensor 266,

the disturbed flux lines 268', as shown in assembly 260' in Fig. 19B, may be altered such that they no longer pass through sensor 266 due to the interaction with vertebrae 270. Alternatively, the field lines 268 passing through sensor 266 may be altered in strength as vertebrae 270 passes.

[0105] Fig. 20 shows yet another variation in which discrete magnets may be placed on each individual vertebrae of an endoscope assembly. As shown, sensor assembly 280 shows only the vertebrae 282 of an endoscope for clarity. Discrete magnets 284 having a first orientation may be placed on alternating vertebrae 282 while magnets 286 having a second orientation may be placed on alternating vertebrae 282 inbetween magnets 284. Thus, when the endoscope is moved, e.g., along the direction of travel 292, flux lines 288 having alternating directions on each vertebrae 282 can be sensed by sensor 290. The measured alternating flux lines may be used as an indication of endoscope movement in a first or second direction. Each of the magnets may be positioned along the periphery of the vertebrae on a single side; however, they may also be positioned circumferentially, as described below in further detail.

[0106] Figs. 21A and 21B show side and cross-sectional views, respectively, of another alternative in magnet positioning. Fig. 21A shows a side view of endoscope assembly 300 in which a number of magnets 304 having a first orientation may be positioned circumferentially about endoscope 302. A number of magnets 306 having a second orientation opposite to the first orientation may also be positioned circumferentially about endoscope 302 separated a distance, d , longitudinally away from magnets 304. With discrete magnets positioned circumferentially about endoscope 302, the rotational orientation of endoscope 302 becomes less important as it passes sensor 308 in determining the insertion depth of the device. Fig. 21B shows a cross-sectional view of the device of Fig. 21A and shows one example of how magnets 304 may be positioned about the circumference. Although this variation illustrates magnets 304 having a "N" orientation radially outward and a "S" orientation radially inward of endoscope 302, this orientation may be reversed so long as the adjacent set of circumferential magnets is preferably likewise reversed. Moreover, although seven magnets are

shown in each circumferential set in the figure, any number of fewer or more magnets may be used as practicable.

[0107] Fig. 22A shows yet another variation in which endoscope 310 may have discrete circumferentially positioned magnets 312 placed at each vertebrae 312 on an outer surface of the endoscope 310. As endoscope 310 is passed into anus 20, Hall sensor 314 may be positioned adjacent to anus 20 such that sensor 314 is able to read or measure the discrete magnets 312 as they pass into anus 20. Fig. 22B shows yet another variation in which endoscope assembly 320 may have endoscope 322 in which individual vertebrae 326 may have some ferromagnetic material 328 integrated or mounted onto or within the vertebrae 326. The ferromagnetic material 328 may be in the form of a band, coating, or other non-obstructive shape for integration onto vertebrae 326 or for coating over portions of vertebrae 326. A sheath or skin 324 may be placed over the vertebrae 326 to provide for a lubricious surface. Inbetween vertebrae 326, non-magnetic regions 330 may be maintained to provide for the separation between vertebrae 326 and between ferromagnetic material 328. Moreover, ferromagnetic material 328 may be applied retroactively not only to endoscopes having vertebrae, but also other conventional endoscopes for which a determination of insertion depth is desired. As endoscope 322 passes magnet 332, sensor 334 may detect disturbances in flux lines 336 as the regions having the ferromagnetic material 328 passes. Additionally, endoscope 322 may be passed at a distance, h , from sensor 334 which is sufficiently close to enable an accurate measurement but far enough away so as not to interfere with endoscope 322 movement.

[0108] Fig. 23 shows yet another variation in which conventional endoscopes may be used with any of the Hall sensor datum devices described herein. As shown, elongate support or tool 337 may have a number of magnets 338, or ferrous material or other materials that may alter or affect a magnetic field, positioned along the tool at predetermined intervals. Magnets 338 may be positioned along the length of tool 337 such that the adjacent magnets are either alternating in polarity or uniform in polarity. Furthermore, magnets 338 may be made integrally within the tool 337 or they may be made as wireforms or

- 30 -

members which may be crimped about tool 337. Tool 337 may be positioned within the working lumen 339 of any conventional endoscope for use with a datum device as described herein. The inclusion of the tool 337 may then enable the determination of insertion depth of a conventional or instrumented endoscope. If a conventional endoscope is used, tool 337 may be securely held within the working lumen 339 during an exploratory procedure. Tool 337 may optionally be removed during a procedure to allow for the insertion of another tool and then reinserted within lumen 339 at a later time to proceed with the insertion and/or withdrawal of the endoscope.

[0109] Figs. 24A to 24C show perspective views of alternative variations for attaching permanent magnets, ferrous materials, or other materials that may alter or affect a magnetic field, onto individual vertebrae. Fig. 24A shows one variation in which vertebrae 340 may be manufactured with a notch or channel 342 circumferentially defined along its outer surface 344. A ring made of a ferrous material or other material that may alter or affect a magnetic field, such as permanent magnets, may be placed within notch 342. Fig. 24B shows another variation in which a formed ring 348 made of a permanent magnet or other such materials may be separately formed and attached onto vertebrae 346. Fig. 24C shows yet another variation in which a wire form 354 made from a ferrous material or other material that may alter or affect a magnetic field, such as a permanent magnet, may be placed within notch 352 of vertebrae 350. Alternatively, ferrous powder may be molded into a circumferential shape and placed within notch 352. Another alternative may be to simply manufacture the entire vertebrae from a ferrous metal or simply cover a vertebrae or a portion of the vertebrae with a ferrous coating.

[0110] Another alternative for utilizing Hall sensors is seen in Figs. 25A and 25B. The variation in Fig. 25A may have a fixed platform 360 upon which a magnet 364 may be mounted. A pressure sensor or microforce sensor 362 may be placed inbetween magnet 364 and platform 360. As an endoscope is passed adjacent to magnet 364, the magnet 364 may be attracted to vertebrae 366 as it passes adjacently. Vertebrae 366 may optionally include ferrous materials or

other materials that may alter or affect a magnetic field as described above to enhance the attraction and/or repulsion. As magnet 364 is pulled or repulsed by the magnetic force, pressure sensor 362 may record the corresponding positive or negative force values for correlating to endoscope insertion depth. Fig. 25B shows another example in which magnets 368 may be attached to a pressure gauge 370, e.g., a Chatillon® gauge made by Ametek, Inc. As the endoscope passes magnets 368 at some distance, h , the attraction and/or repulsion between magnets 368 and vertebrae 366 may be accordingly measured by gauge 370 and similarly correlated to endoscope insertion depth.

[0111] Yet another variation is shown in Figs. 26A and 26B in assembly 380. Rather than utilizing the linear motion of an endoscope past a static datum, a rotatable datum 382 may be used to record insertion length. Datum wheel 382 may be configured to rotate about pivot 384 while sensing the movement of endoscope 386, which shows only schematic representations of the vertebrae for clarity. The datum wheel 382 may have a number of magnets 398 incorporated around the circumference of wheel 382. Each magnet may be arranged in alternating pole configurations or alternatively in the same pole arrangement. Each of the magnets 398 are also preferably spaced apart from one another at intervals equal to the linear distances between the magnets 388, 390 or permanent magnet located along the body of endoscope 386. Ferrous materials, or materials that may otherwise alter a magnetic field, may be used in place of the permanent magnets. As endoscope 386 is moved past datum wheel 382, wheel 382 rotates in corresponding fashion with the linear movement of endoscope 386 past the datum 382.

[0112] The rotation of datum wheel 382 that results when endoscope 386 is moved past can be sensed by a variety of methods. One example includes rotary optical encoders, another example includes sensing the movement of magnets 398 on datum wheel 382 as they rotate relative to a fixed point as measured by, e.g., Hall effect sensors or magnetoresistive sensors. As datum wheel 382 rotates with the linear movement of endoscope 386, datum wheel 382 may directly touch endoscope 386 or a thin material may separate the wheel 382

from the body of endoscope 386. Fig. 26B shows one variation of an assembly view of datum wheel 382 which may be rotatably attached to housing 392. Housing 392 may be connected to stem or support 394, which may extend from housing 392 and provide a support member for affixing datum wheel 382 to the patient, an examination table, a stand, or any other platform. Support 394 may also be used to route any cables, wires, connectors, etc., to housing 392 and/or datum wheel 382. The associated sensors and various support electronics, e.g., rotary encoders, magnetic field sensors, etc., may also be located within housing 392. Support 394 may further include an optional flexible joint 396 to allow datum wheel 382 to track the movement of endoscope 386 as it passes into or out of a patient.

EXAMPLES OF EXTERNAL SENSING DEVICES

[0113] The external sensing devices, or datum, may function in part as a point of reference relative to a position of the endoscope and/or patient, as described above. The datum may accordingly be located externally of the endoscope and either internally or externally to the body of the patient. If the patient is positioned so that they are unable to move with any significant movement during a procedure, the datum may function as a fixed point of reference by securing it to another fixed point in the room, e.g., examination table, procedure cart, etc. Alternatively, the datum may be attached directly to the patient in a fixed location relative to the point of entry of the endoscope into the patient's body. The datum variations described herein may utilize any of the sensing and measurement methods described above.

[0114] For instance, for colonoscopic procedures the datum may be positioned on the patient's body near the anus. The location where the datum is positioned is ideally a place that moves minimally relative to the anus because during such a procedure, the patient may shift position, twitch, flex, etc., and disturb the measurement of the endoscope. Therefore, the datum may be positioned in one of several places on the body.

[0115] One location may be along the natal cleft, i.e., the crease defined between the gluteal muscles typically extending from the anus towards the lower back. The natal cleft generally has little or no fat layers or musculature and does not move appreciably relative to the anus. Another location may be directly on the gluteal muscle adjacent to the anus.

[0116] One variation for the datum for positioning along the natal cleft 408 is shown in Fig. 27. Datum 400 may have sensor 402 positioned in the distal tip of the sensing device, which may be placed adjacent to anus 20. The datum itself may be positioned within the natal cleft 408 and temporarily held in place on the patient with adhesive 406. The datum may have a connector 404 extending via a wire or cable for connection to a processor (not shown).

[0117] Another variation is shown in Fig. 28 in which the datum 410 may have a base comprising a substrate. The substrate may have an adhesive side that may be placed against the small of the patient's back. An elongate flexible member or arm 412 may extend from the substrate and lie within or against the natal cleft such that the distal end 414 of member 412 is adjacent to anus 20. Distal end 414 may have a sensor mounted within for sensing the movement of an endoscope as it is passed through anus 20. The flexible member 412 may be secured along the natal cleft using, e.g., adhesive tape, to prevent excessive movement of the device.

[0118] Figs. 29A and 29B show a detailed view of a variation of the datum device 410 of Fig. 28. Fig. 29A shows another view for possible positioning of datum 410 on patient 18. The substrate may be positioned proximal of anus 20 while member 412 extends along the natal cleft for positioning sensor tip 414 proximally adjacent to anus 20. Fig. 29B shows datum 410 laid out and having a substrate 420 upon which sensors and electronics may be positioned. Substrate 420, as mentioned above, may have an adhesive backing for temporary placement against the patient 18. Moreover, datum 410, or any of the other datum examples described herein, may be optionally configured to be disposable for one-time use on a patient. Support electronics 422 may optionally be placed upon substrate 420 and sensor 426 may be positioned within the distal

- 34 -

end 414 at or near the end of the flexible member or arm 412. An optional magnet 428 may be positioned along member 412 proximally of sensor 426. Connector 424 may extend via a wire or cable from datum 410 for connection to a processor.

[0119] Another variation is shown in Figs. 30A and 30B which shows datum substrate 430 having sensor 436 positioned within the distal end of elongate flexible assembly 434 for placement adjacent to anus 20. Connector 432 may be provided for connection to a processor. Here, elongate assembly 434 may be secured against or within the natal cleft by use of, e.g., an adhesive strip 438. Fig. 30B shows a cross-sectional top-down view of elongate assembly 434 positioned against the natal cleft. A sponge, silicone wedge, or some other wedging device 440 may be positioned inbetween elongate assembly 434 and adhesive strip 438 to ensure secure positioning of the datum device relative to anus 20.

[0120] Fig. 31 shows another variation on the datum device which may utilize a disposable substrate. Datum assembly 450 may have substrate 452 for placement against the patient. A retaining pocket 454 may be defined within or upon substrate 452 and it may be configured to allow for a reusable electronic sensor assembly 458 to be placed within pocket 454. Sensor assembly 458 may have a wire or cable 462 extending therefrom and it may further have a sensor 460 positioned or potted upon sensor assembly 458. The sensor assembly 458 may be positioned within pocket 454 by slipping sensor assembly 458 through an opening 456 defined within substrate 452 and sensor assembly 458 is preferably positioned within pocket 454 such that sensor 460 is positioned at the distal end of substrate 452 to allow for positioning adjacent the anus.

[0121] Another variation for positioning a datum is directly on the gluteal muscle adjacent to the anus. Generally, the sensor and associated circuitry may be incorporated into a patch or small chassis that may then be attached to the muscle adjacent to the anus. The entire datum assembly may optionally be mounted onto a bandage-like package with an adhesive backing. Figs. 32A and 32B show a variation in datum 470 which is formed into a small chassis having

connector 472 extending therefrom. Datum 470 may be attached temporarily to patient 18 via adhesive 474 adjacent to anus 20. A guide, ramp, or other similar structure 476 for situating, orienting, or guiding endoscope relative to datum 470 may be optionally incorporated into the device.

[0122] Fig. 33A shows another variation of the device in datum 480. In this example, datum 480 may be in the form of a patch with sensor 482 positioned thereon. The device may be placed upon one of the gluteal muscles such that sensor 482 is adjacent to anus 20. Fig. 33B shows a detailed view of how datum 480 may be positioned upon the gluteal muscle adjacent to anus 20. Adhesive 484 may be placed over datum 480 to temporarily hold it onto the gluteal muscle as shown. Fig. 33C shows an example of how datum 480 may interact with endoscope 486 as it is advanced or withdrawn from anus 20. Because datum 480 may have a relatively small diameter, D, discomfort may be reduced for the patient and close proximity to anus 20 may be assured. As endoscope 486 moves past datum 480, the sensors within datum 480 may measure the insertion depth. Zone 488 shows generally the zone of operation, i.e., the region within which the operator's or surgeon's hands generally operate during a colonoscopy procedure. Because of the small diameter of datum 480 and its position adjacent anus 20, it is generally out of the way of the operator or surgeon during a procedure and thereby allows for unhindered operation of the endoscope 486 while maintaining accurate measurement or sensing with datum 480.

[0123] Fig. 34 shows yet another variation in datum 490 which may have a substrate with sensor 494 mounted at one end. Support electronics 492 may be optionally mounted on datum 490 and wire or cable 496 may be used to transmit the measured signals from sensor 494. Datum 490 may be in a triangular shape for placement upon a single gluteal muscle, as shown, such that a vertex of the substrate is positioned adjacent to anus 20 to allow sensor 494 to sense or measure signals as endoscope 498 is advanced or withdrawn into anus 20. Although shown in this variation in a triangular pattern, this is not intended to be limiting and is intended merely to illustrate one possible shape for the datum.

[0124] Another variation is shown in Fig. 35 in which datum 500 may incorporate multiple sensors. Datum 500 may be placed on a single gluteal muscle and it may define an insertion region 508 at which the anus of the patient may be positioned. Each of the sensors 502, 504, 506 may thereby be configured to sense or read the endoscope as it passes through or past the insertion region 508. Although three sensors are shown in this configuration, fewer or more sensors may be utilized depending upon the configuration of the datum 500 and the desired signal processing results.

[0125] Fig. 36 shows yet another variation in which datum 510 may be encased in a rigid housing. Datum 510 may thus encapsulate support electronics 512 within with sensor 514 directed towards one end of the housing. The housing may incorporate a connector 516 attached via a wire or cable extending from the datum 510. The rigid housing may be temporarily adhered to the patient on a gluteal muscle in the same fashion as described above.

[0126] Fig. 37 shows yet another variation in which datum 520 may be configured to extend across the natal cleft to position an opening defined in the datum over the anus of the patient. As shown, an adhesive substrate 522 may be configured, e.g., into a "butterfly" configuration. Substrate 522 may have at least two wings or flaps 524 for adhering to each gluteal muscle across the natal cleft while sensor 526 and support electronics 528 may be contained adjacent an opening 534 defined at or near the center of substrate 522. Sensor 526 and support electronics 528 may be potted or contained within a housing 530 on substrate 522. Connector 532 may be attached via a wire or cable for connection to a processor.

[0127] A datum device may also be configured to encircle an endoscope as it passes into the body. Such a datum configuration may be useful when using sensing technology such as RF. In the case of RF, the datum may be in a looped configuration to facilitate the exchange of RF signals with components or sensors mounted along the endoscope, as described above. One variation of a looped datum configuration is shown in Figs. 38A and 38B. As shown, datum 540 may have a loop 542 defined at a distal end to function as a signal receiver, e.g., RF

signals, and/or as a guide loop. The datum 540 may be aligned along the natal cleft 408 and secured in place with adhesive tape 544. A connector 546 may be attached to datum 540 via a wire or cable at a first end of datum 540 while sensor 548 may be positioned at the opposing end of datum 540. Sensor 548 may be positioned adjacent to anus 20, while loop 542 encircles the opening of anus 20. The loop 542 may define an insertion region 550 through which an endoscope may be passed. The loop 542 may be made of a thin, flexible material such as mylar and it optionally have an adhesive backing for placement upon the tissue surrounding anus 20. Although shown in a circle configuration, loop 542 may be in a variety of looped configuration and is not limited by its shape.

[0128] Yet another variation is shown in Fig. 39 where a supporting garment 560, e.g., a pair of underpants, may define an opening 562 in the region surrounding the anus 20. A loop 564 may be incorporated into the fabric such that the loop surrounds the opening 562. The fabric in the middle of loop 564 may either be removable at the time of the procedure or omitted altogether. Connection to the loop 564 may be made through connector 566, which can be connected via a wire or cable extending from, e.g., the waistband, front, or side of garment 560.

[0129] Aside from colonoscopy, other applications may include uses in minimally invasive surgery (MIS). MIS typically depends upon the use of long, thin tools for insertion into the body via small incisions, e.g., often through a cannula. Instruments typically employed during MIS may include rigid endoscopes, laparoscopes, thorascopes, needle drivers, clamps, etc. Because each of these tools must pass through an opening in the body, a datum device may be used adjacent to that body opening for tracking instrument insertion depth. In situations where cannulas are used, the cannula itself may be instrumented through one of the methods described above.

[0130] For other types of endoscopy procedures, various types of flexible endoscopes may be used, e.g., upper endoscopes, duodenoscopes, sigmoidoscopes, bronchoscopes, neuroscopes, ENT scopes, etc. Any of the devices and methods described above may be utilized and configured to maintain insertion depth for

any of these types of endoscopes. For instance, for flexible endoscopes that enter the body transorally, a mouthpiece configured as a datum may be utilized.

[0131] The applications of the devices and methods discussed above are not limited to regions of the body but may include any number of further treatment applications. Other treatment sites may include other areas or regions of the body. Additionally, the present invention may be used in other environments such as exploratory procedures on piping systems, ducts, etc. Modification of the above-described assemblies and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

CLAIMS

We claim:

1. An apparatus for determining a position of an elongate instrument insertable into a cavity, comprising:
at least one sensor adapted to be positioned adjacent to the elongate instrument; and
at least one magnetic field source positioned adjacent to the sensor,
wherein the sensor is further adapted to detect a motion of the elongate instrument when the instrument is advanced or withdrawn relative to the sensor.
2. The apparatus of claim 1 wherein the apparatus is adapted to be fixed relative to a position of the cavity.
3. The apparatus of claim 2 wherein the apparatus is positioned upon or within a body of a patient such that the sensor is in a fixed position relative to the cavity.
4. The apparatus of claim 2 wherein the apparatus is positioned on a platform external to a body of a patient such that the sensor is in a fixed position relative to the cavity.
5. The apparatus of claim 1 wherein the sensor comprises a conductor through which an electrical current is flowable.
6. The apparatus of claim 1 wherein the sensor is positioned between the magnetic field source and the elongate instrument.
7. The apparatus of claim 1 further comprising an additional sensor adjacent to the at least one sensor.

8. The apparatus of claim 1 wherein the sensor is positioned at a predetermined distance from the elongate instrument.

9. The apparatus of claim 1 wherein the magnetic field source comprises a permanent magnet.

10. The apparatus of claim 1 wherein the magnetic field source comprises an electromagnet.

11. The apparatus of claim 1 wherein the sensor is positioned perpendicularly to a magnetic field generated by the magnetic field source .

12. The apparatus of claim 1 wherein the elongate instrument comprises a plurality of ferromagnetic material or magnet positioned along at least a portion of a length of the instrument.

13. The apparatus of claim 12 wherein each of the ferromagnetic material or magnet is positioned along the length such that adjacent magnets are alternating in polarity.

14. The apparatus of claim 12 wherein each of the ferromagnetic material or magnet is positioned along the length such that adjacent magnets are uniform in polarity.

15. The apparatus of claim 12 wherein each of the ferromagnetic material or magnet is positioned at a predetermined distance from one another.

16. The apparatus of claim 12 wherein each of the ferromagnetic material or magnet is configured to be secured about the elongate instrument.

17. The apparatus of claim 12 wherein at least one of the ferromagnetic materials or magnets comprises a unique magnetic signature indicative of its position along the instrument.

18. The apparatus of claim 17 wherein each of the ferromagnetic materials or magnets comprises a unique magnetic signature each indicative of its position along the instrument.

19. The apparatus of claim 1 further comprising an elongate tool having a plurality of ferromagnetic material or magnet positioned along at least a portion of a length of the tool, wherein the tool is adapted to be inserted within a working channel of the elongate instrument.

20. The apparatus of claim 19 wherein each of the ferromagnetic material or magnet is positioned along the length of the tool such that adjacent magnets are alternating in polarity.

21. The apparatus of claim 19 wherein each of the ferromagnetic material or magnet is positioned along the length of the tool such that adjacent magnets are uniform in polarity.

22. The apparatus of claim 19 wherein each of the ferromagnetic material or magnet is positioned at a predetermined distance from one another.

23. The apparatus of claim 19 wherein each of the ferromagnetic material or magnet is configured to be secured about the elongate tool.

24. The apparatus of claim 1 further comprising a pressure sensor disposed adjacent to the magnetic field source for sensing a pressure from the magnetic field generator when the instrument is advanced or withdrawn relative to the sensor.

25. The apparatus of claim 1 further comprising a plurality of additional magnetic field sources disposed about a circumference of a rotatable platform, the platform being in communication with the sensor.

26. The apparatus of claim 25 wherein each of the magnets is positioned about the circumference such that adjacent magnets are alternating in polarity.

27. The apparatus of claim 1 further comprising a connector attached to the sensor.

28. The apparatus of claim 1 further comprising a substrate upon which the sensor is mountable.

29. The apparatus of claim 28 wherein the substrate comprises an adhesive backing for temporarily adhering to a surface.

30. The apparatus of claim 28 wherein the substrate comprises an elongate and flexible member upon which the sensor is mountable.

31. The apparatus of claim 28 wherein the substrate defines a pocket thereon, the sensor being removably positionable within the pocket.

32. The apparatus of claim 28 wherein the substrate is adapted for placement adjacent a single side of a natal cleft defined on a body.

33. The apparatus of claim 28 wherein the substrate is adapted for placement across a natal cleft defined on a body.

34. The apparatus of claim 33 wherein the substrate defines an access opening therein through which the elongate instrument is insertable.

35. The apparatus of claim 1 wherein the apparatus is disposable in an undergarment to be worn by a patient.

- 44 -

36. An instrument configured to determine a position of the instrument within a cavity, comprising:

an elongate device having a proximal portion and a selectively steerable distal portion; and

at least one electrically conductive circuit disposed along at least a portion of a length of the elongate device;

wherein the circuit is adapted to indicate an insertion depth of the elongate device within the cavity by indicating a change within the circuit indicative of a position along the length where the elongate device enters the cavity.

37. The instrument of claim 36 wherein the at least one electrically conductive circuit comprises a continuous circuit along at least the portion of the length.

38. The instrument of claim 36 wherein the at least one electrically conductive circuit comprises a flexible circuit disposed within an outer member of the elongate device.

39. The instrument of claim 28 wherein the at least one electrically conductive circuit is adapted to electrically couple with a grounding electrode positioned externally of the cavity.

40. The instrument of claim 39 wherein the grounding electrode comprises a pad.

41. The instrument of claim 39 wherein the electrically conductive circuit is adapted to inductively couple with the grounding electrode.

42. The instrument of claim 39 wherein the electrically conductive circuit is adapted to capacitively couple with the grounding electrode.

- 45 -

43. The instrument of claim 36 wherein the at least one electrically conductive circuit comprises a plurality of electrically conductive switches located at predetermined intervals from one another along at least the portion of the length of the elongate device.

44. The instrument of claim 43 wherein each switch is adapted to close the conductive circuit upon the switch entering the cavity such that a closed switch is indicative of the position along the length where the elongate device enters the cavity.

45. The instrument of claim 43 wherein each switch is adapted to sense a change in an output selected from the group consisting of pressure, capacitance, conductivity, moisture, pH, temperature, light intensity, resistance, and photoresistance.

46. The instrument of claim 36 wherein the at least one electrically conductive circuit comprises a plurality of electrically conductive leads extending distally along the length such that at least two corresponding leads terminate at each of a plurality of predetermined locations along the length.

47. The instrument of claim 36 wherein the at least one electrically conductive circuit comprises a plurality of conductive contacts located at predetermined locations along the length, wherein each adjacent contact is positioned at a predetermined distance from one another such that the conductive circuit is closed upon adjacent contacts entering the cavity.

48. The instrument of claim 36 wherein the circuit is further adapted to indicate a portion of the elongate device external to the cavity.

49. An apparatus for determining a position of an elongate instrument insertable into a cavity, comprising:
a substrate for positioning upon or within a body of a patient; and
at least one sensor positionable upon the substrate such that the sensor is adjacent to an opening into the body,
wherein the sensor is adapted to detect a motion of the elongate instrument when the instrument is advanced or withdrawn through the opening.
50. The apparatus of claim 49 further comprising at least one magnetic field source positionable upon the substrate.
51. The apparatus of claim 50 wherein the magnetic field source is positioned adjacent to the sensor.
52. The apparatus of claim 49 wherein the sensor is adapted to be fixed relative to the opening.
53. The apparatus of claim 49 wherein the sensor comprises a pressure sensor adapted to contact the elongate instrument and detect pressure changes as the instrument is advanced or withdrawn.
54. The apparatus of claim 49 wherein the sensor is further adapted to detect a change in a diameter of the elongate instrument when the instrument is advanced or withdrawn through the opening.
55. The apparatus of claim 54 wherein the sensor is further adapted to maintain contact with the elongate instrument and move accordingly when the change in diameter is detected.
56. The apparatus of claim 49 wherein the substrate comprises an adhesive backing for temporarily adhering to the body.

- 47 -

57. The apparatus of claim 49 wherein the substrate comprises an elongate and flexible member upon which the sensor is mountable.

58. The apparatus of claim 49 wherein the substrate defines a pocket thereon, the sensor being removably positionable within the pocket.

59. The apparatus of claim 49 wherein the substrate is adapted for placement adjacent a single side of a natal cleft defined adjacent the opening.

60. The apparatus of claim 49 wherein the substrate is adapted for placement across a natal cleft defined on the body.

61. The apparatus of claim 49 wherein the substrate is adapted for placement along or within the natal cleft defined on the body.

62. The apparatus of claim 49 wherein the substrate defines an access opening therein through which the elongate instrument is insertable.

63. The apparatus of claim 49 wherein the apparatus is disposable in an undergarment to be worn by the patient.

64. A method of determining a position of an elongate instrument insertable into a cavity, comprising:

positioning at least one sensor adjacent to an opening of the cavity;
providing a magnetic field adjacent to the sensor;
passing the elongate instrument through the opening adjacent to the sensor such that the magnetic field is altered; and
correlating alterations in the magnetic field to movement of the elongate instrument.

65. The method of claim 64 wherein positioning the at least one sensor comprises positioning the sensor in a fixed relationship relative to the opening.

66. The method of claim 64 wherein positioning the at least one sensor comprises positioning at least an additional sensor adjacent to the opening.

67. The method of claim 64 wherein positioning the at least one sensor comprises positioning the sensor upon or within a body of a patient.

68. The method of claim 64 wherein positioning the at least one sensor comprises positioning the sensor on a platform external to a body of a patient.

69. The method of claim 64 wherein positioning the at least one sensor comprises positioning the sensor between the magnetic field and the elongate instrument.

70. The method of claim 64 wherein positioning the at least one sensor comprises positioning the sensor upon a substrate.

71. The method of claim 70 wherein positioning the at least one sensor comprises positioning the sensor upon an elongate and flexible member extending from the substrate.

72. The method of claim 70 wherein positioning the at least one sensor comprises removably positioning the sensor within a pocket defined by the substrate.

73. The method of claim 64 wherein positioning the at least one sensor comprises placing the sensor adjacent a single side of a natal cleft defined on a body.

74. The method of claim 64 wherein positioning the at least one sensor comprises placing the sensor across a natal cleft defined on a body.

75. The method of claim 64 wherein positioning the at least one sensor comprises placing the sensor along or within a natal cleft defined on a body.

76. The method of claim 64 wherein positioning the at least one sensor comprises positioning the sensor perpendicularly to the magnetic field.

77. The method of claim 64 further comprising passing an electrical current through the sensor prior to or while passing the elongate instrument through the opening.

78. The method of claim 64 wherein providing the magnetic field comprises positioning at least one magnet adjacent to the sensor.

79. The method of claim 64 wherein providing the magnetic field comprises positioning at least one electromagnet adjacent to the sensor.

80. The method of claim 64 further comprising placing a plurality of magnets along the elongate instrument at predetermined locations such that

adjacent magnets are alternating in polarity prior to passing the elongate instrument through the opening.

81. The method of claim 64 further comprising placing a plurality of magnets along the elongate instrument at predetermined locations such that adjacent magnets are uniform in polarity prior to passing the elongate instrument through the opening.

82. The method of claim 64 wherein passing the elongate instrument further comprises altering the magnetic field such that the field is not steady through the sensor.

83. The method of claim 64 wherein correlating alterations in the magnetic field comprises determining an insertion depth of the elongate instrument during advancement or withdrawal through the opening.

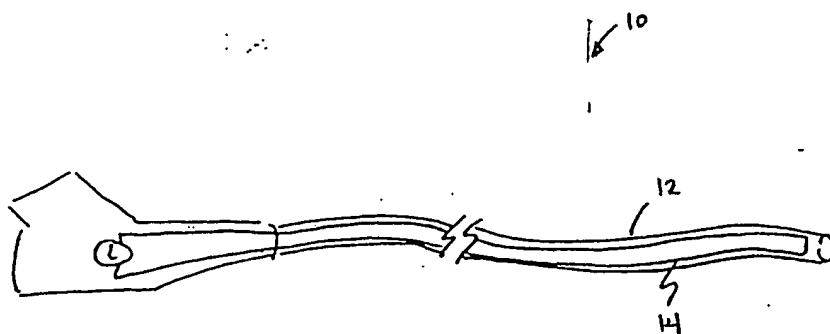


FIG. 1A

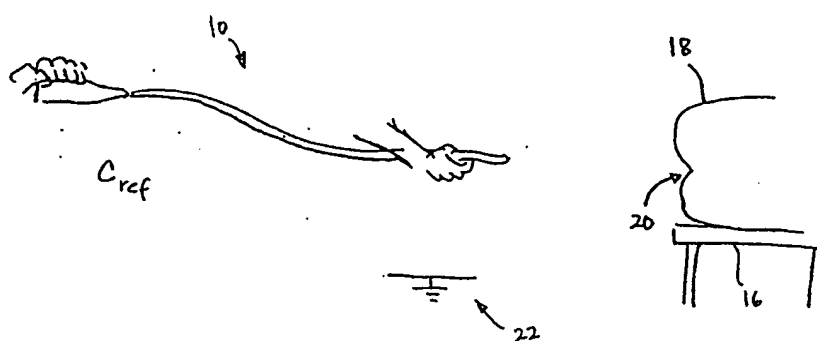


FIG. 1B

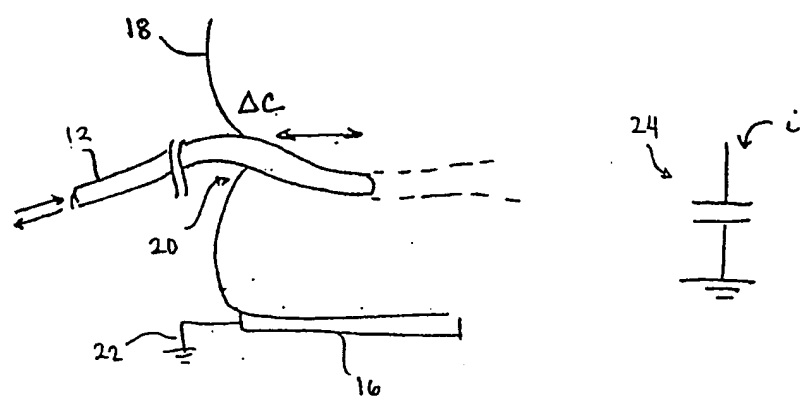


Fig. 1C

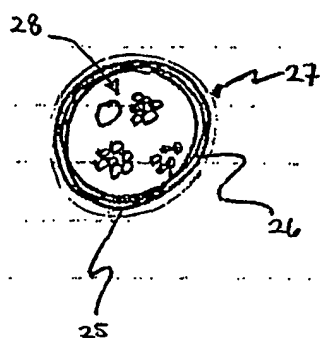


Fig. 1D

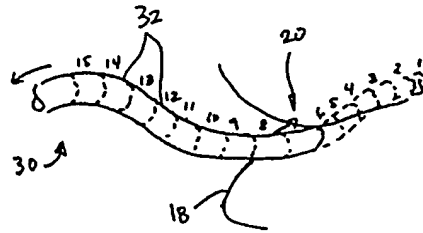


FIG. 2A

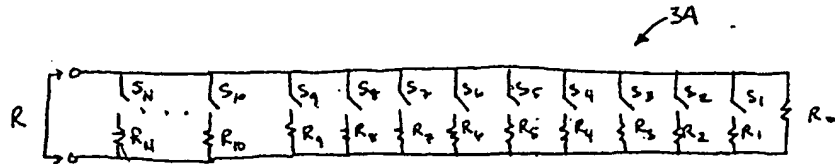


FIG. 2B

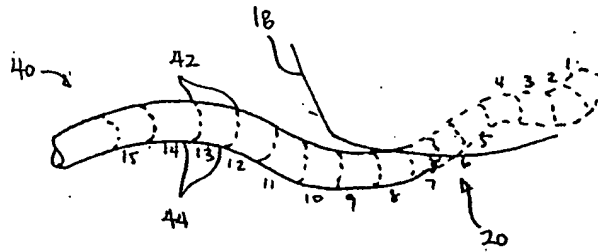


FIG. 3A

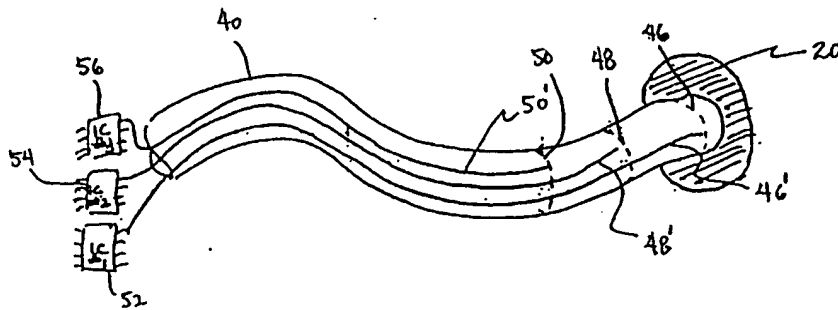


FIG. 3B

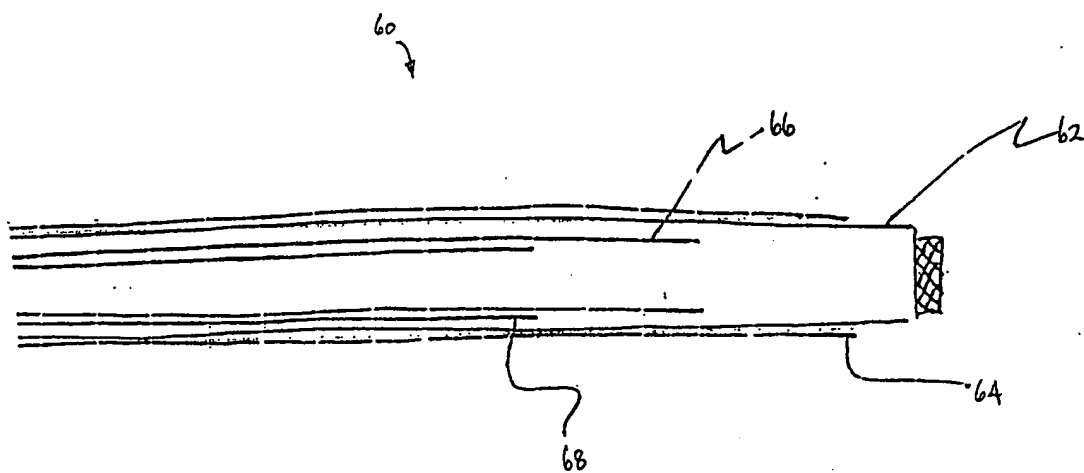


Fig. 4

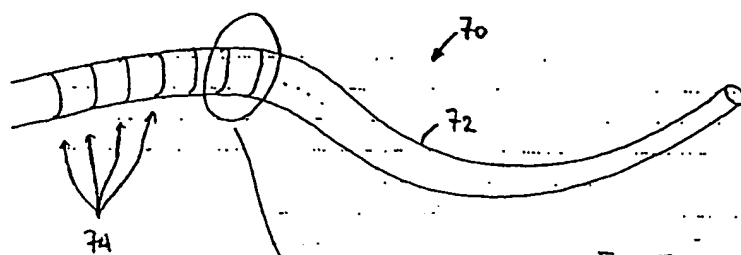


FIG. 5A

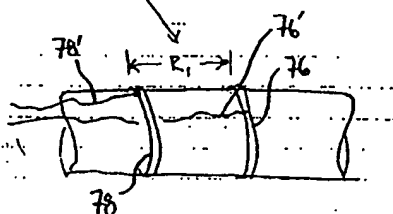


FIG. 5B

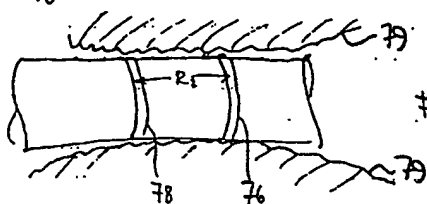


FIG. 5C

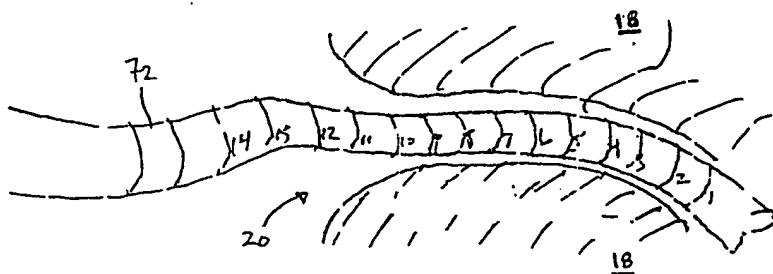


FIG. 5D

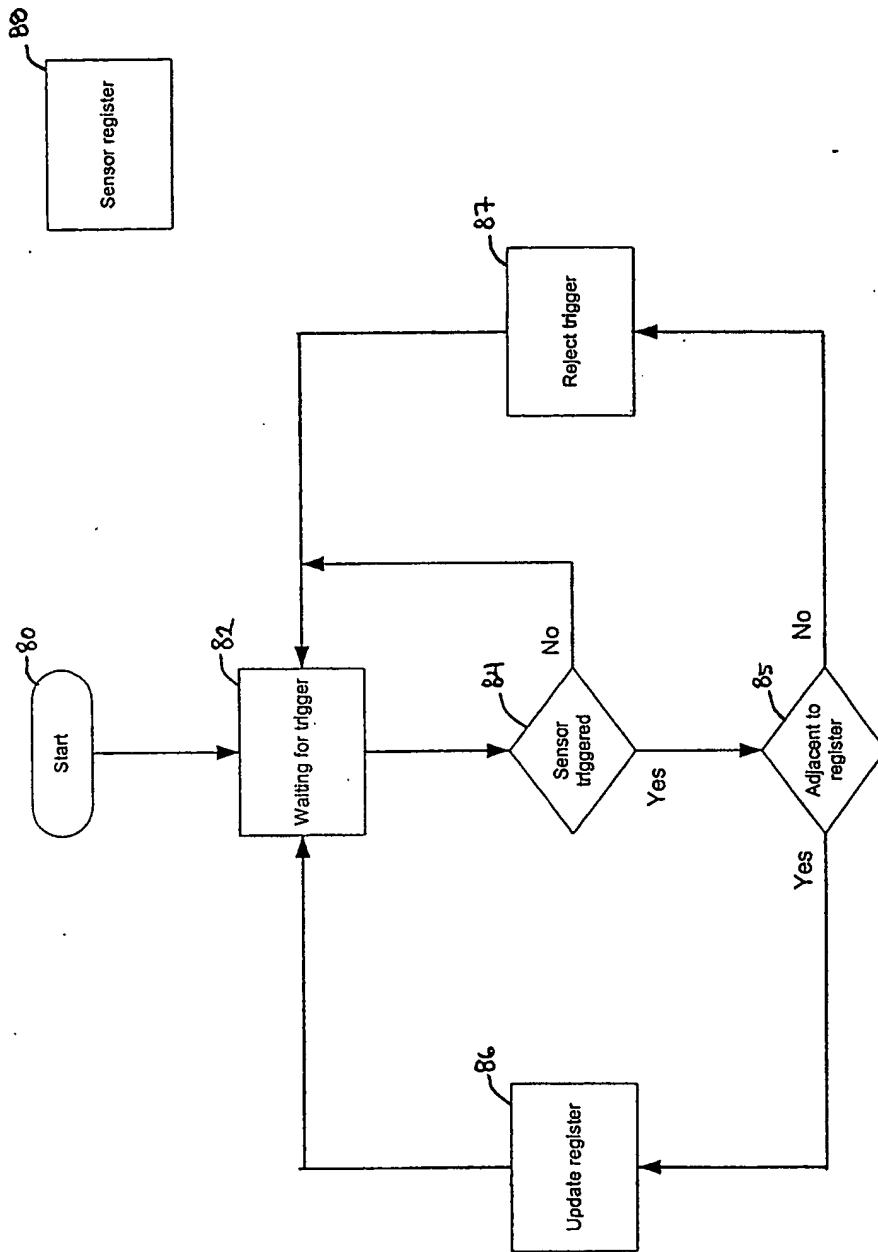


Fig. 6

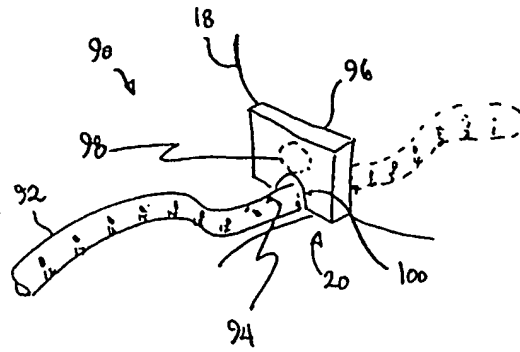


FIG. 7A

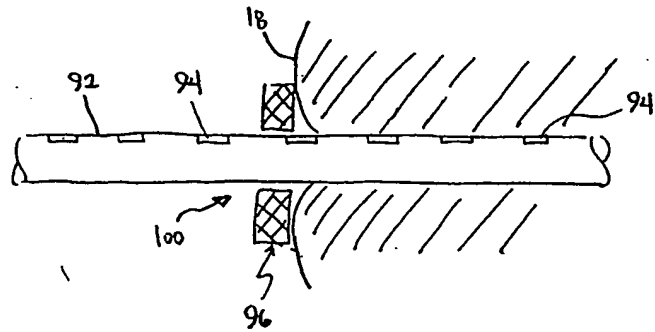


FIG. 7B

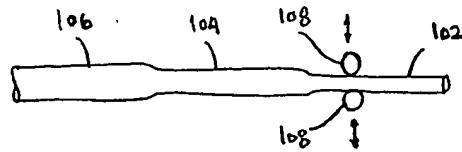


FIG. 7C

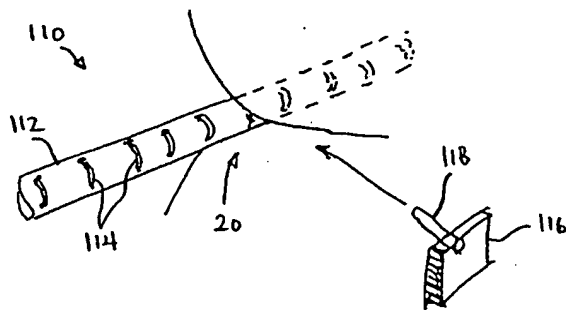


FIG. 8

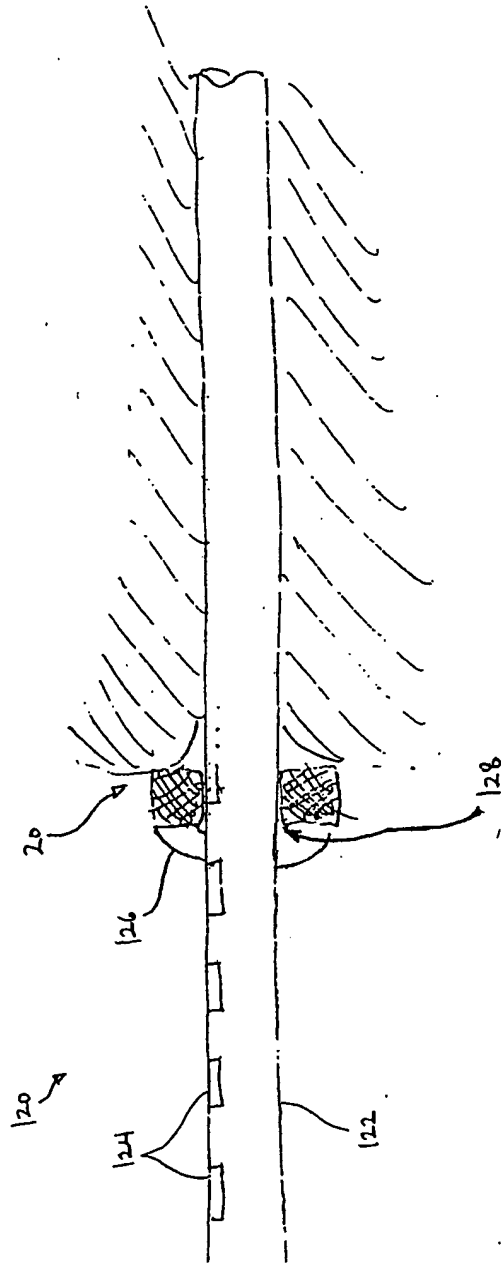


Fig. 9

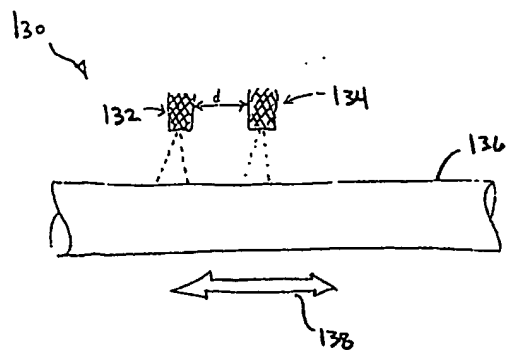


FIG. 10

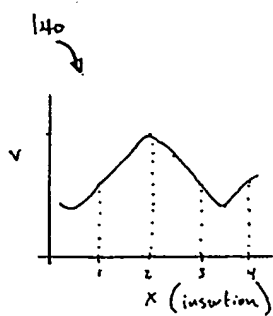


FIG. 11A

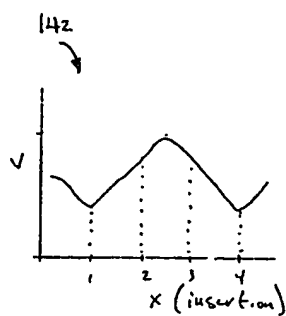


FIG. 11B

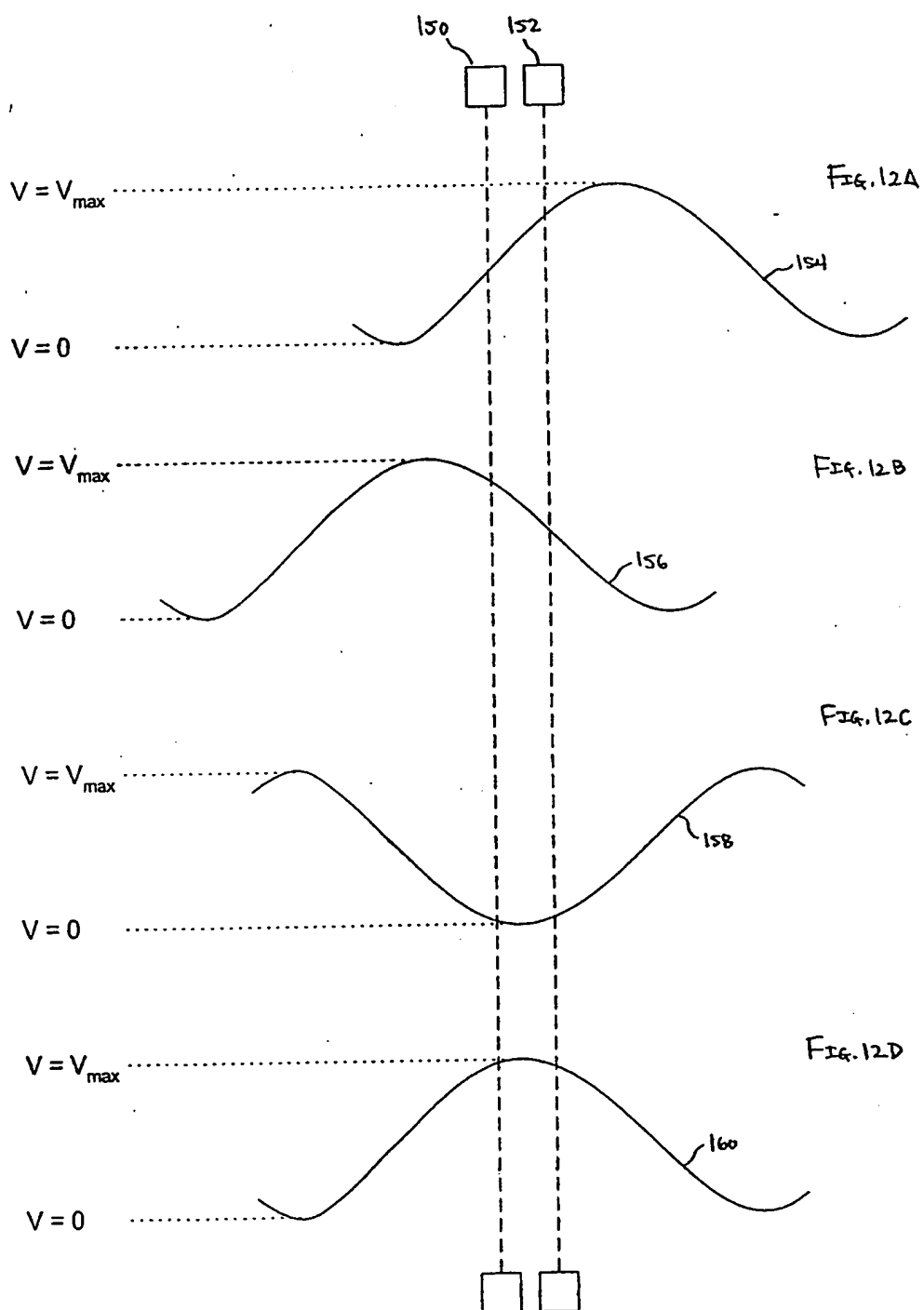
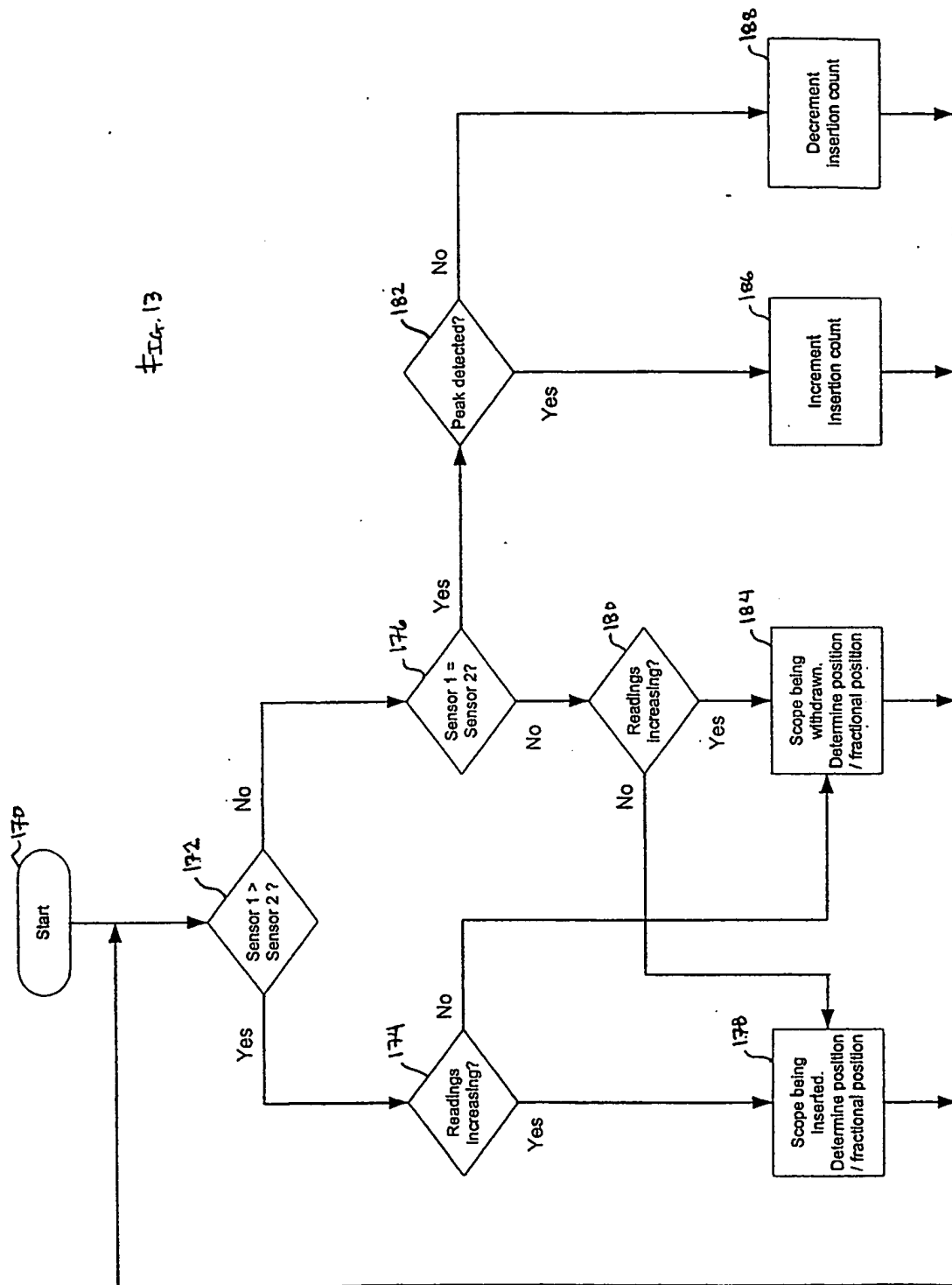


Fig. 13



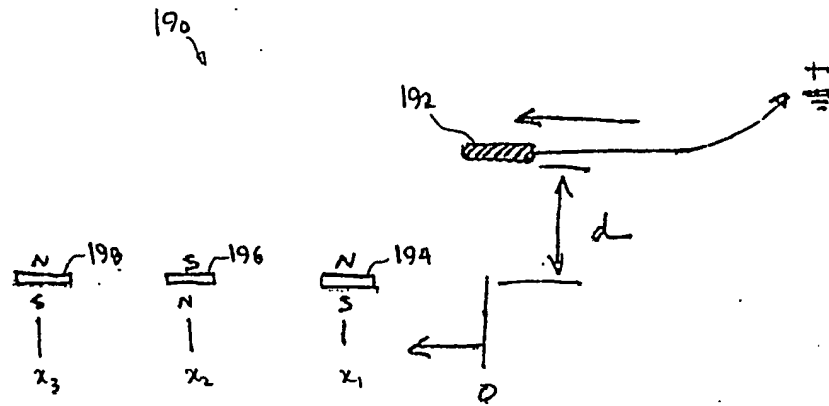
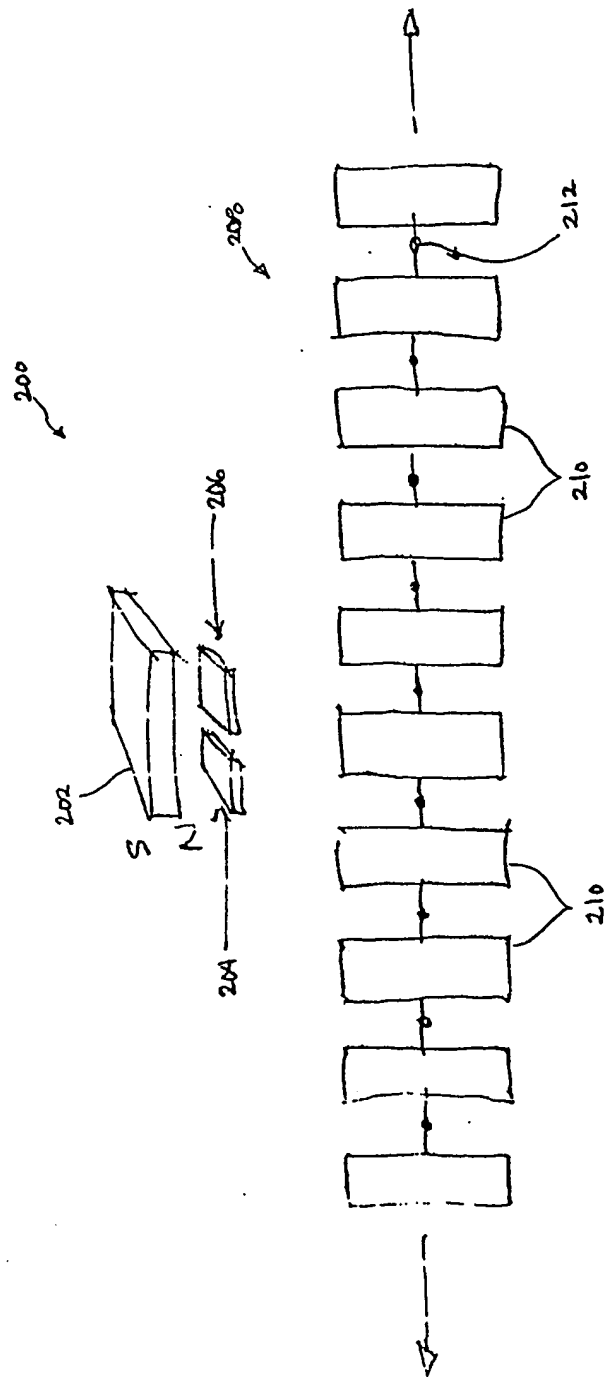


Fig. 14



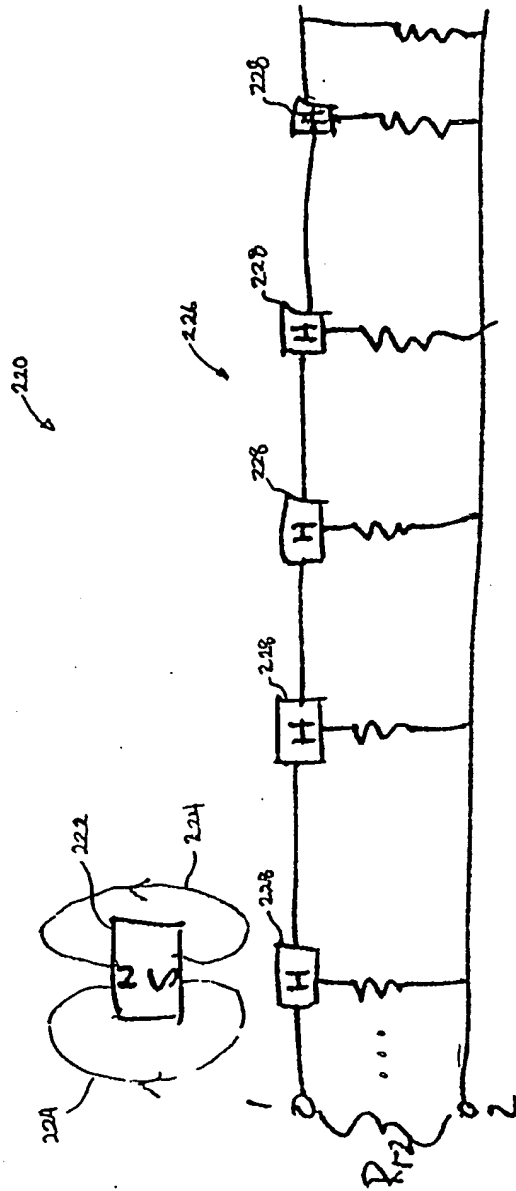


Fig. 16

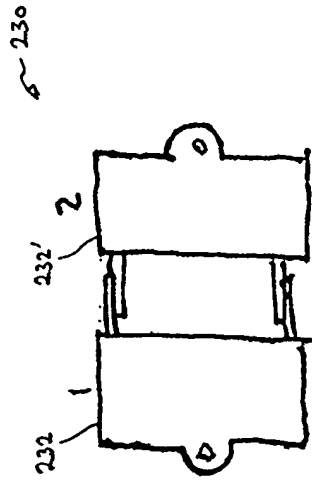


Fig. 17A

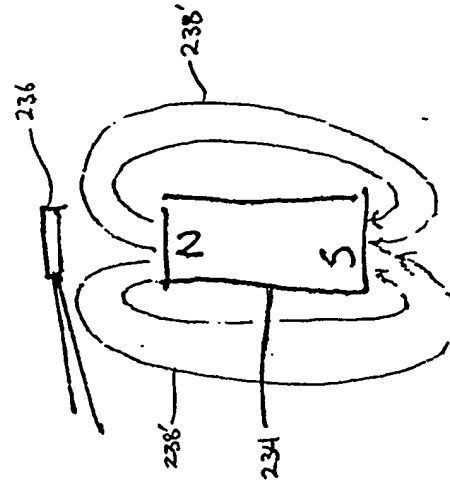


Fig. 17B

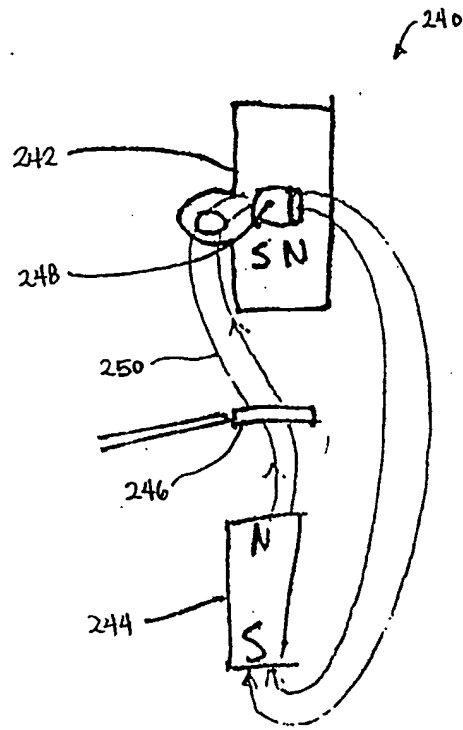


FIG. 18

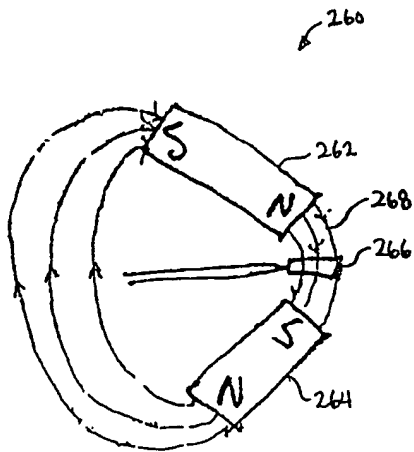


FIG. 19A

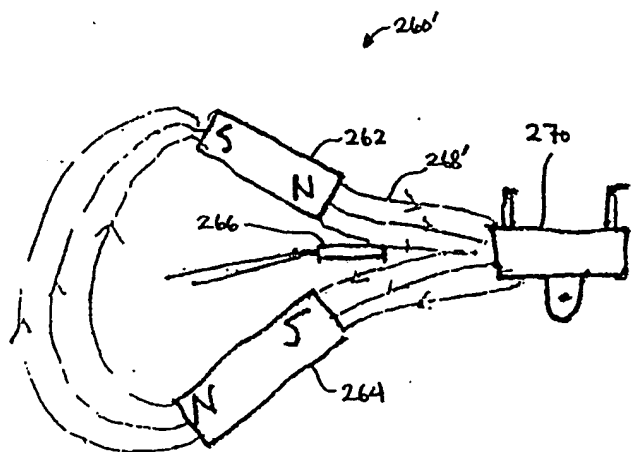


FIG. 19B

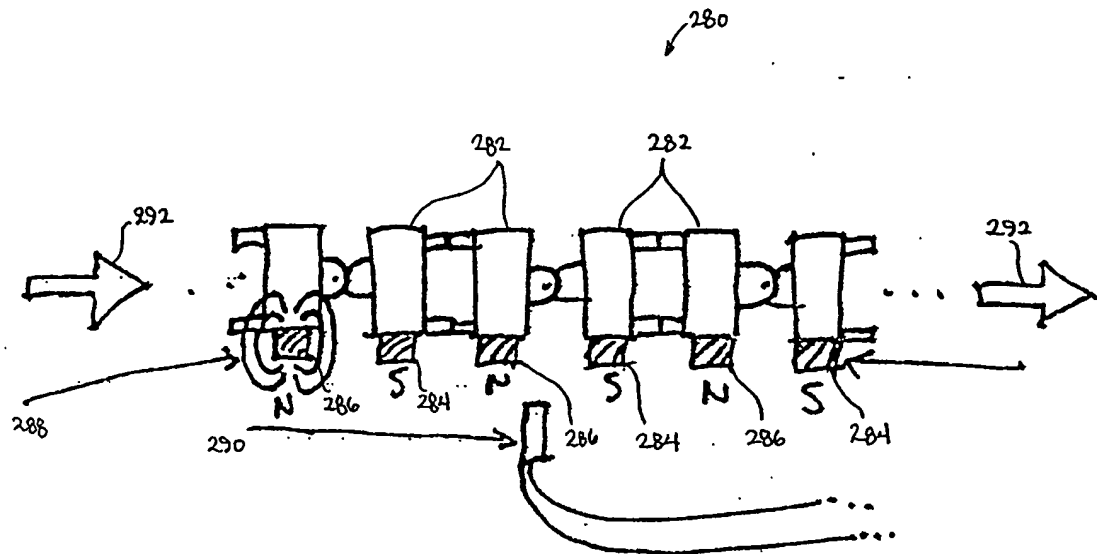


FIG. 20

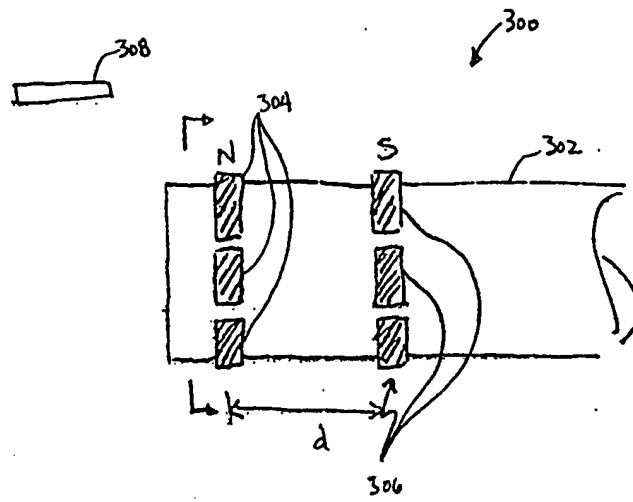


FIG. 21A

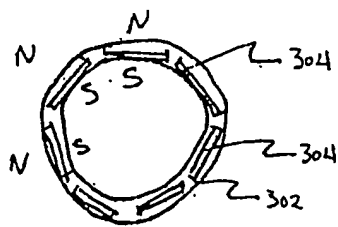


FIG. 21B

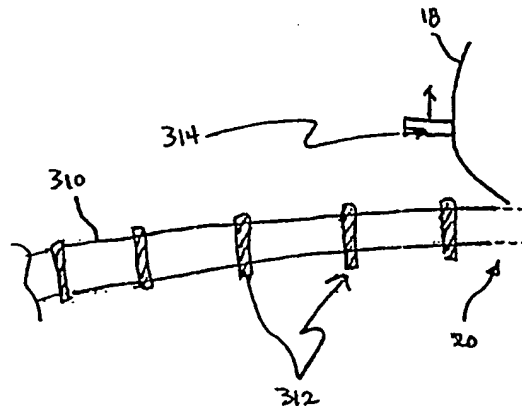


FIG. 22A

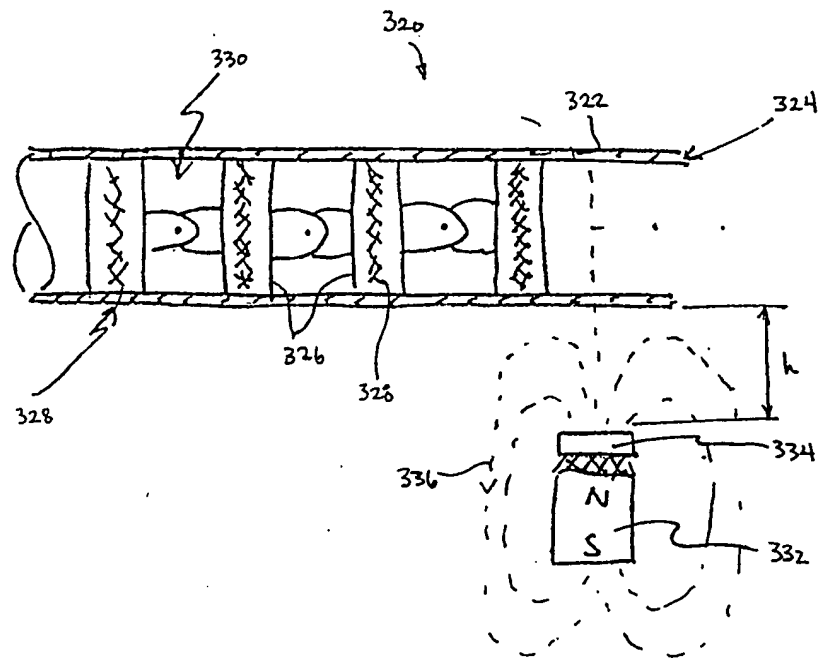


FIG. 22B

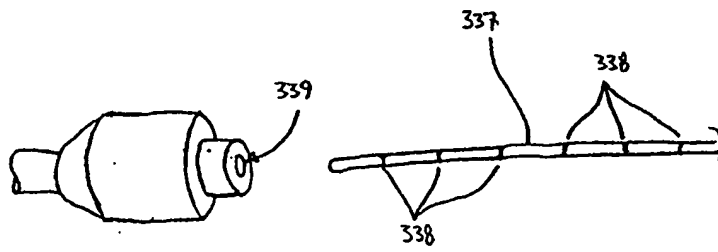


FIG. 23

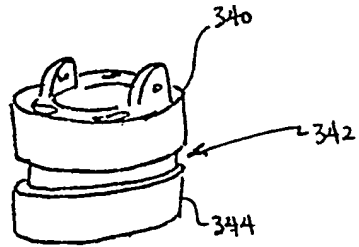


FIG. 24A

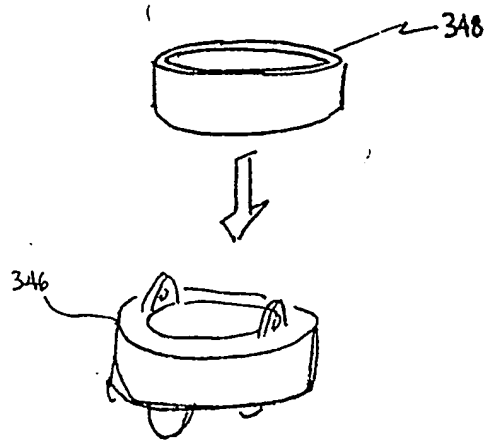


FIG. 24B

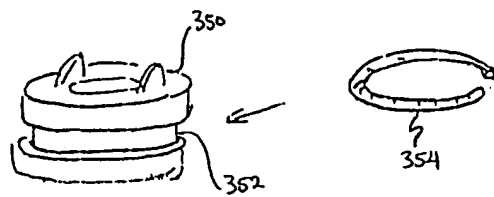


FIG. 24C

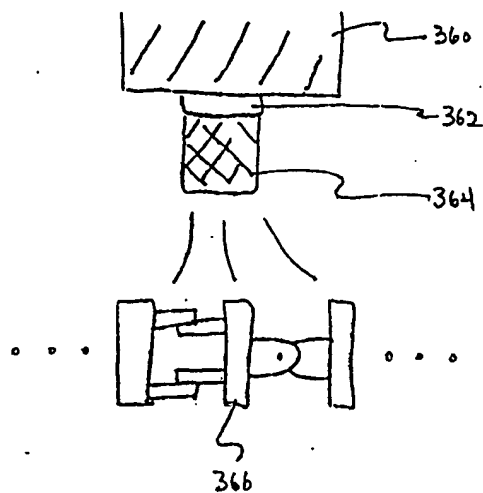


FIG. 25A

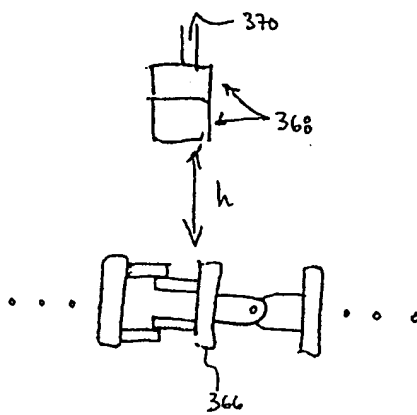


FIG. 25B

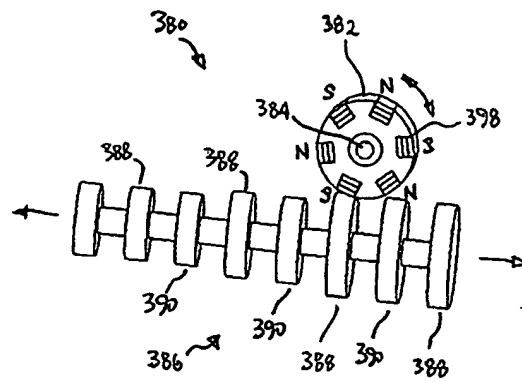


FIG. 26A

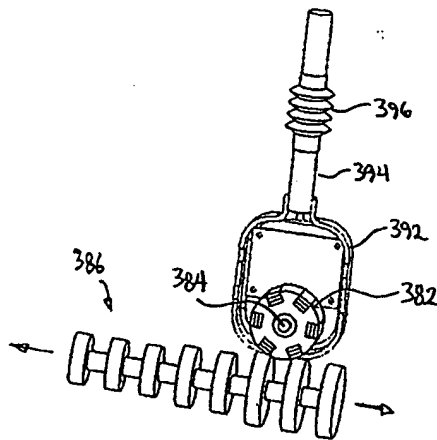


FIG. 26B

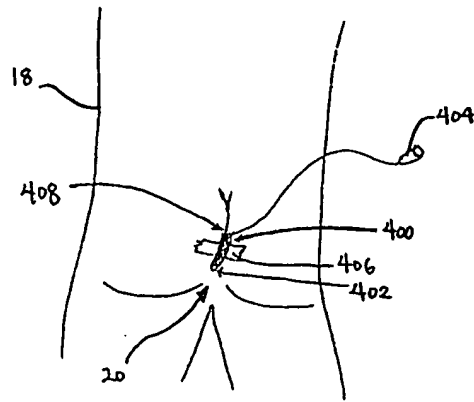


FIG. 27

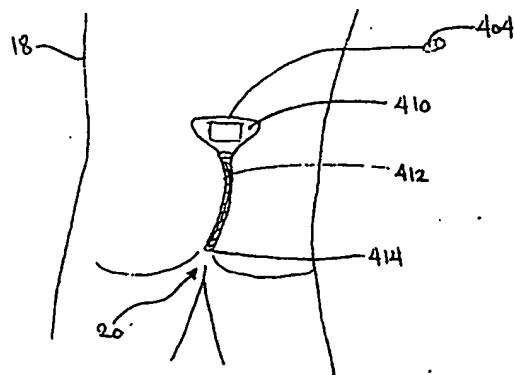


FIG. 28

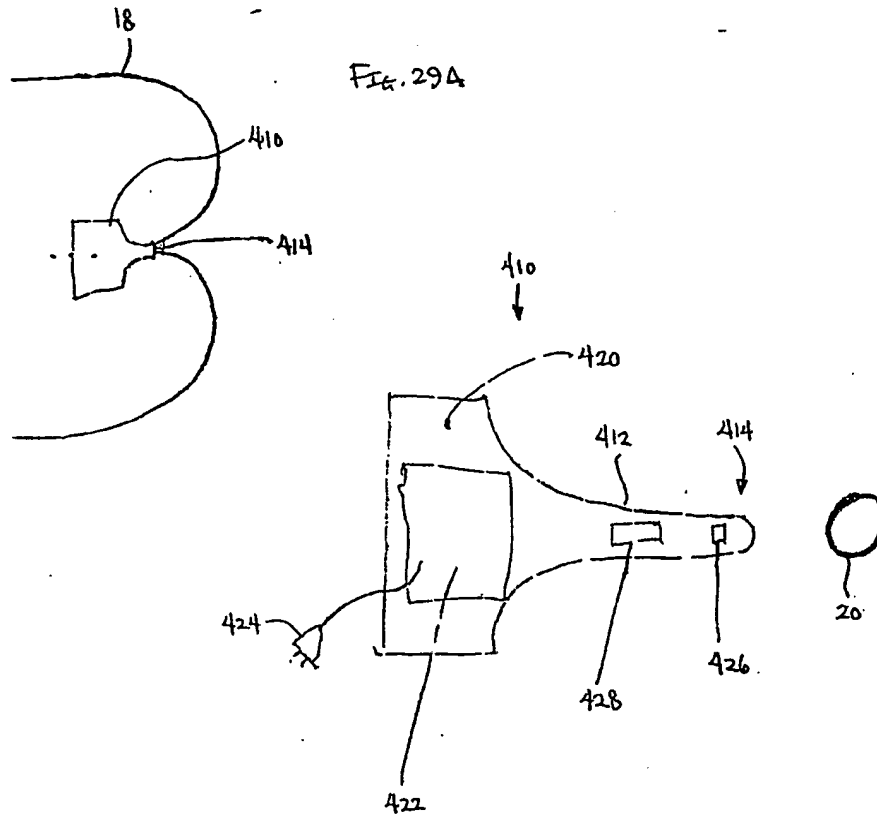
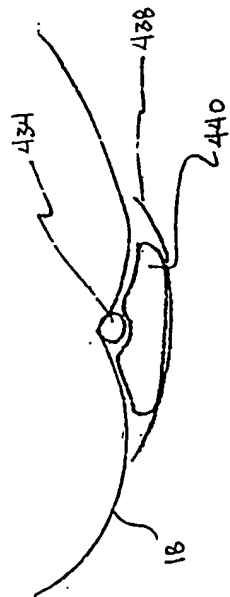
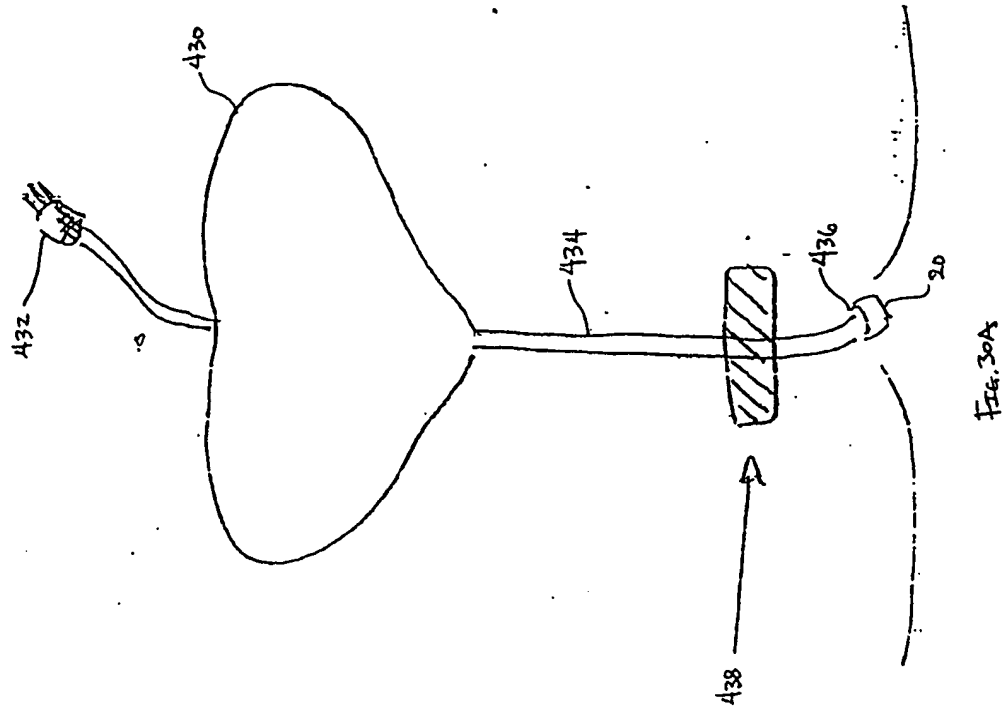


FIG. 298



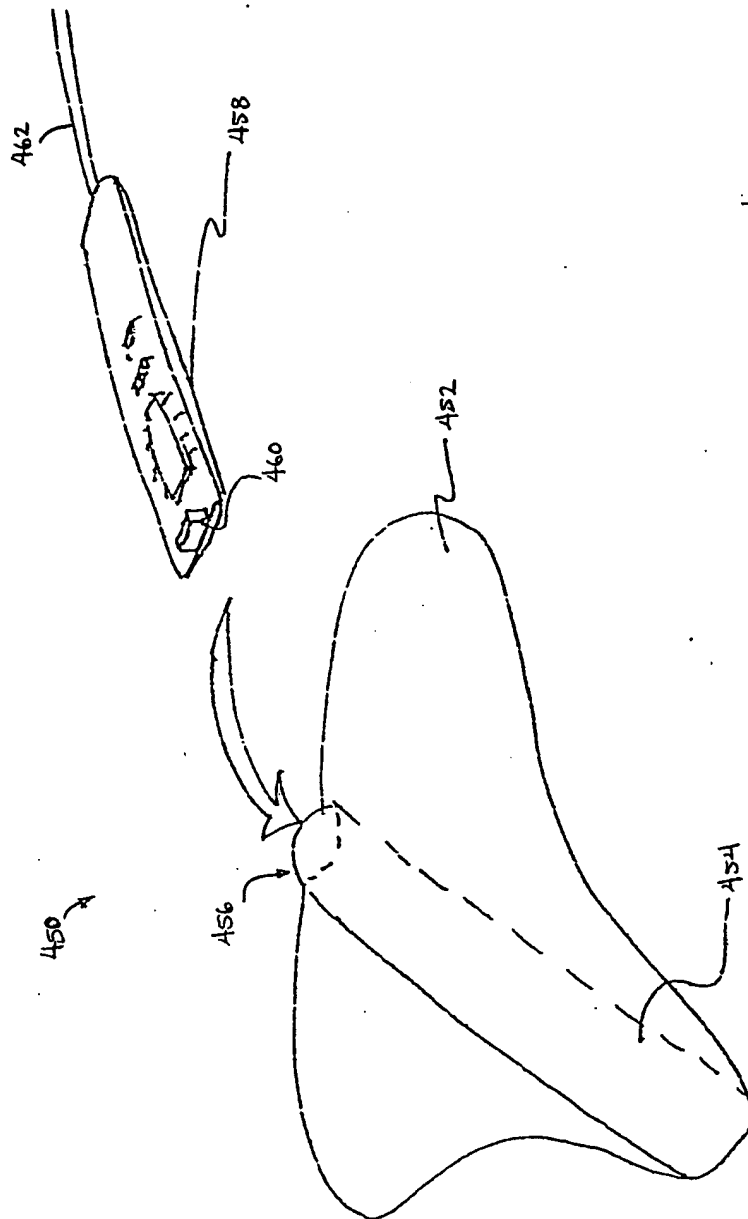


Fig. 31

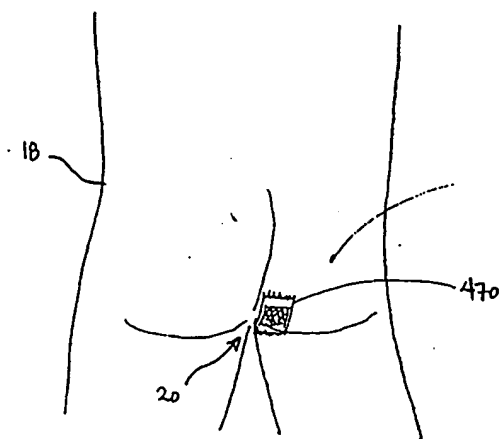


Fig. 32A

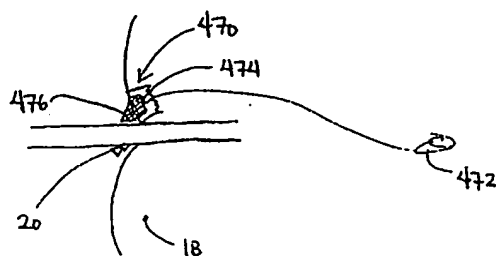


Fig. 32B

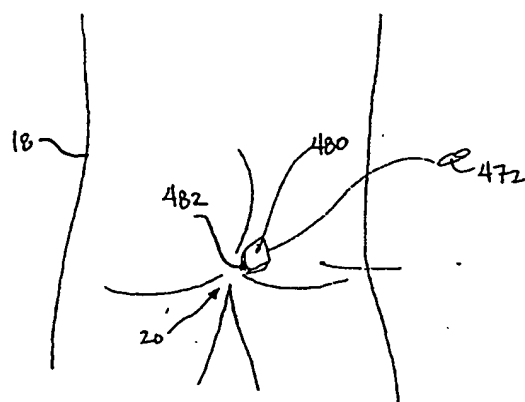


Fig. 33A

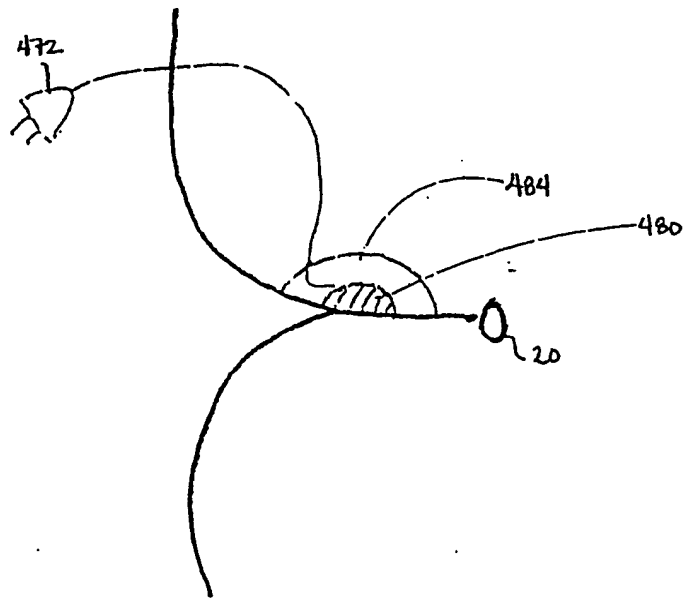


FIG. 33B

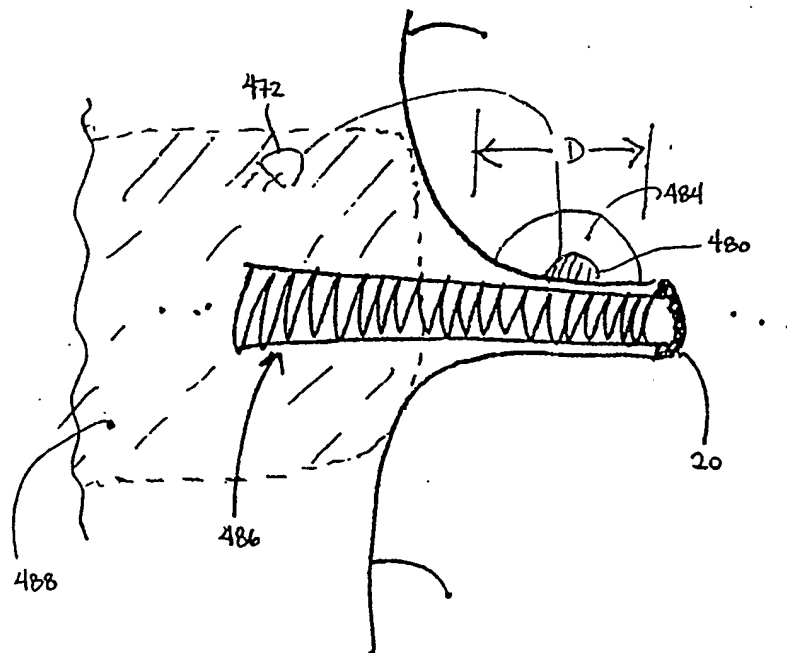


FIG. 33C

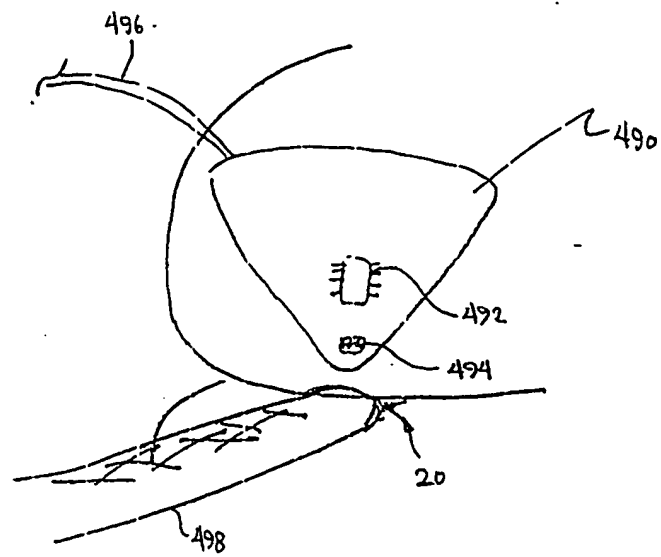


FIG. 34

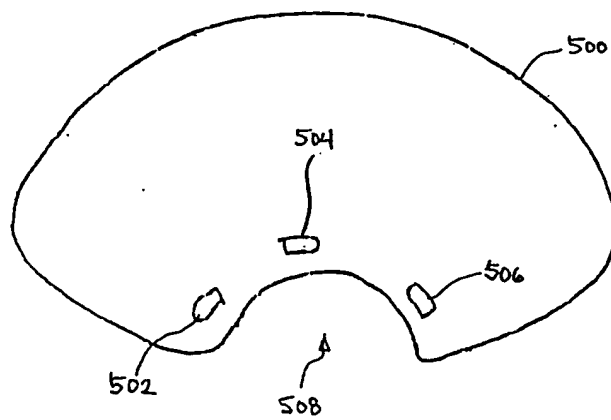


FIG. 35

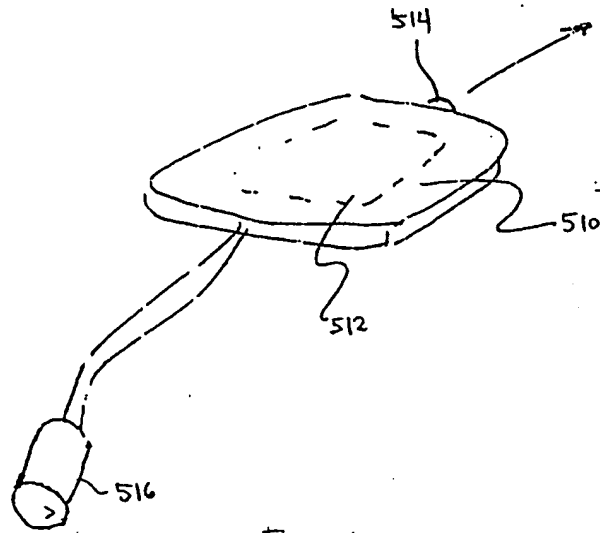


FIG. 36

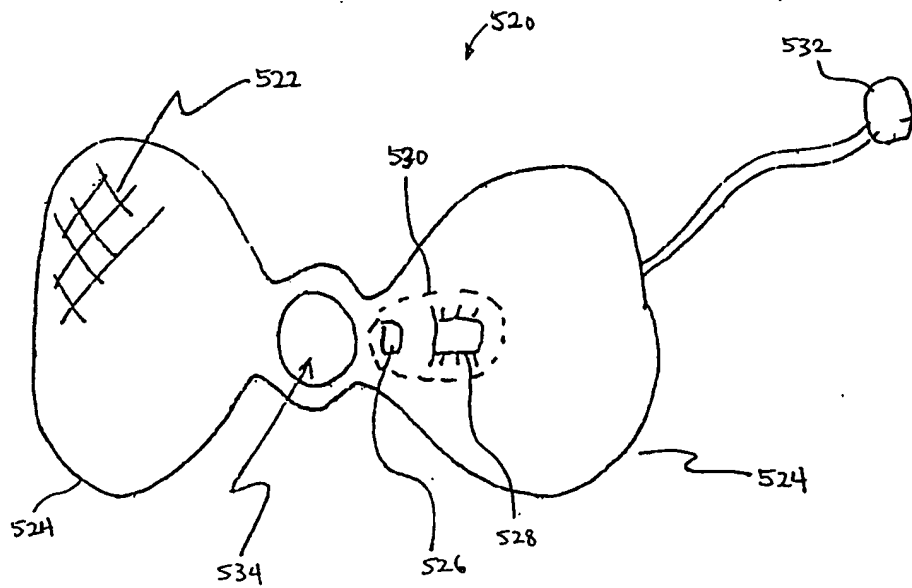


FIG. 37

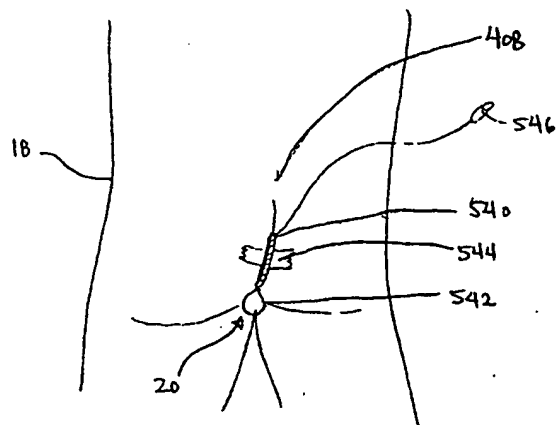


FIG. 38A

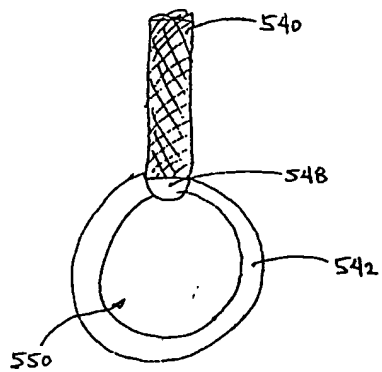


FIG. 38B

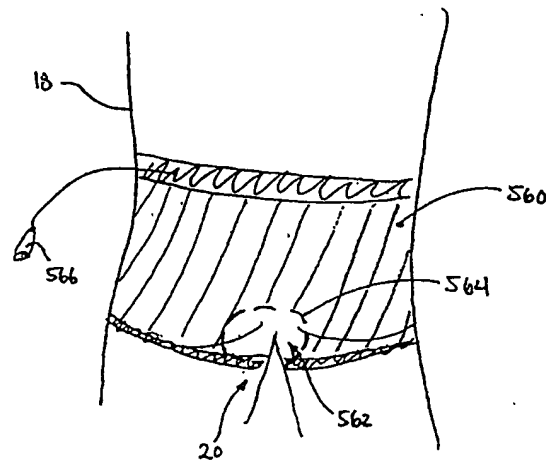


Fig. 39

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.